

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 4-26			
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:			
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2018 Base                      Option Period Number    4			Title of Work Assignment/SF Site Name BOSC Meeting			
Contractor ICF Incorporated, L.L.C.				Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From 11/01/2017 To 10/31/2018			
Comments:									
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund									
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A.									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)  (Cents)	Site/Project (Max 8)	Cost Org/Code
1									
2									
3									
4									
5									
Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee:			LOE:				
11/01/2013 To 10/31/2018									
This Action:									
Total:									
Work Plan / Cost Estimate Approvals									
Contractor WP Dated:				Cost/Fee			LOE:		
Cumulative Approved:				Cost/Fee			LOE:		
Work Assignment Manager Name    Tom Tracy  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code: Phone Number: 202-564-6518 FAX Number:		
Project Officer Name    Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:		
Other Agency Official Name  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code: Phone Number: FAX Number:		
Contracting Official Name    William Yates  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:		

**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 4-26**

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**TITLE:** Board of Scientific Counselors (BOSC) Meeting / Conference Support

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**Specify Section & Paragraph SOW:** E. Risk Assessment Support

1. Science Writing, Risk Communication and Training
2. Administration and Technical Support for NCEA Human Health Related Meetings

**PERIOD OF PERFORMANCE:** November 1, 2017 thru October 31, 2018

**1. BACKGROUND**

The primary functions of the BOSC include evaluating ORD's science and engineering research programs, laboratories, and research-management practices, and recommending actions to improve their quality and/or strengthen their relevance to the mission of the EPA. For more information on the BOSC, go to <http://epa.gov/osp/bosc/>. This work assignment is a follow-on to work performed in the Year 3 Option Period under Work Assignment # 3-26. The work continues from Task 1 through Task 4 during this Year 4 Option Period under Work Assignment 4-26.

**2. PURPOSE**

The purpose of this Work Assignment is to provide: a full range of administrative and logistical support services for the conduct of Federal Advisory Committee meetings, conferences and/or teleconferences related to the Charter of the Office of Research and Development's Board of Scientific Counselors (BOSC); administrative activities required for reports prepared by the BOSC Executive Committee or it's Subcommittees and Workgroups; and the full range of administrative support services for assimilating materials collected from extensive candidate searches conducted for either the Executive Committee, or existing or proposed Subcommittee and Workgroups.

The contractor's activities will not require special expertise in matters of science discussed by the Board, but the contractor should possess the practical knowledge, experience, and skills commonly used in facilitating high-level policy meetings.

Meetings of the BOSC Executive Committee, Subcommittees and Workgroups will generally be held on-site at US EPA (either Headquarters or a Laboratory/Center, as appropriate), if space is available, with the approval of the Designated Federal Officer (DFO). Under this work assignment, it is anticipated that contractor support shall be required for approximately four Executive Committee meetings (at least 1 is expected to be face-to-face meetings); approximately 5 face-to-face program review subcommittee meetings. In addition, contractor support shall be needed for approximately 17 conference calls (expected to be 2-3 hour calls) in support of the Executive Committee, Subcommittee and Workgroup meetings. The EPA WAM will provide the meeting dates via written technical direction.



It is anticipated that approximately 6 reports shall be generated by the BOSC during the timeframe of this work assignment, and that candidate searches requiring contractor support may occur no more than 2 times per year.

### **3. STATEMENT OF WORK**

This Statement of Work describes EPA's requirements regarding services to be rendered by the contractor for BOSC meeting and conference support. The contractor shall provide the necessary personnel and resources in the following four areas for the BOSC:

1. Pre-meeting communication and logistical support.
2. On-site technical support during meetings/teleconferences.
3. Prepare summary minutes of meetings/teleconferences.
4. Word processing for reports.

#### **Task 1. Pre-meeting communication and logistical support**

As requested by the EPA WAM, the contractor shall prepare a BOSC member's background binder for the list of invitees provided by the EPA WAM, to include agenda, minutes of last meeting (if appropriate), other background/logistical material needed for the meeting/teleconference. Via written technical direction, the meeting/teleconference dates will be provided by the EPA WAM. The contractor shall prepare a mail merge file and address labels for the list of members and invitees. All correspondence shall be transmitted under the Designated Federal Officer's name. It is anticipated that there will be approximately 30 participants for each Executive Committee meeting, and approximately 20-100 participants for each Subcommittee face-to-face meeting.

The contractor shall obtain meeting space facilities when government owned facilities are not available, as determined by the EPA WAM (this includes negotiation with hotels or other entities to obtain meeting space, as well as reservations (room blocks) for lodging that fall within U.S. Government per-diem rates and meet Agency lodging requirements).

#### **Task 2. On-site technical support during meetings/teleconferences**

The contractor shall provide recorders to take minutes at each meeting/teleconference. The contractor shall ensure that all equipment needed at the meeting is available, to include microphone equipment, laptop computers, etc., as needed and specified by the EPA WAM.

The contractor shall provide a registration table each day of the meeting and shall provide table tents and name badges of participants. The contractor shall also photocopy additional sets of handouts and materials as may be required during the course of the meeting, on a fast turnaround basis, as requested by the EPA WAM.

The contractor shall deliver to the EPA WAM any materials not distributed at the meeting or materials left behind by BOSC members within two working days after the meeting.

### **Task 3. Prepare summary minutes of meetings/teleconferences**

The contractor shall prepare and submit to the EPA WAM draft minutes of the meetings/teleconferences within 15 working days of the end of each meeting/teleconference. The contractor shall incorporate comments and changes to the minutes per written technical direction by the EPA WAM and submit final minutes within 5 working days of receiving EPA comments. The draft and final minutes shall be provided in electronic format (Word is the Agency standard software).

### **Task 4. Word Processing for Reports**

The contractor shall provide word processing support for any reports prepared by the BOSC Executive Committee or its Subcommittees. The contractor shall not be involved in developing the technical content of the report, and shall not provide any scientific technical expertise. The contractor shall only provide word processing services to compile, format, edit (based on Executive Committee and Subcommittee member input, plus any factual changes requested by ORD and approved by the Executive Committee), and finalize reports prepared by the Executive Committee or its Subcommittees.

The contractor shall compile/format/edit and submit draft Executive Committee/ Subcommittee reports to the EPA WAM within 15 working days after receiving report content. The contractor shall incorporate comments and changes to the reports and submit final reports to the EPA WAM within 5 working days of receiving comments. The draft and final reports shall be provided in electronic format (Word is the Agency standard software).

## **5. SCHEDULE OF DELIVERABLES**

<b>Product</b>	<b>Due Date</b>
Logistical Arrangements of Meeting	60 working days prior to meeting
Draft Minutes of Meeting (To EPA WAM)	15 working days after completion of meeting
Final Minutes of Meeting (to EPA WAM)	5 working days after receipt of comments from EPA WAM
Draft Exec Committee/Sub- committee reports (to	15 working days after receipt of report EPA WAM) content from EPA WAM
Final Exec Committee/Sub- committee reports (to	5 working days after receipt of comments EPA WAM) from EPA WAM

## **6. SPECIAL CONDITIONS**

Final products shall be produced by the Contractor upon EPA WAM's approval through written technical direction. The Contractor shall provide all materials written under these tasks to the EPA WAM, as

per work assignment, in electronic form. Electronic version shall be compatible with the ORD's computer systems and software, (e.g., Microsoft Word).

Separate from the Monthly Progress Report, the contractor costs shall be provided to the EPA WAM on a monthly basis, and shall be compiled separately for the Executive Committee and each Subcommittee. EPA is required to annually input cost information for each committee or subcommittee into a government-wide database, and EPA will not be able to comply with this federal requirement unless contractor costs are tracked and reported to EPA by each committee/subcommittee.

## **7. CONFIDENTIALITY**

Some of the work assigned under these tasks may be to draft, edit, and review program and sensitive organizational information that will not be ready for broad or public distribution. The contractor shall not discuss the contents of any document with anyone not specified as a participant in the documents review process or its preparation. The EPA WAM will supply the contractor with a list of individuals involved with any documents under these tasks.

## **8. MANAGEMENT CONTROLS**

Periodic meetings between the EPA and contractor work assignment managers are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WAM's discretion, these meetings may occur via teleconference or video conferences. The contractor shall document these meetings and submit copies of this correspondence to the EPA WAM.

The EPA WAM may identify one or more EPA technical representatives for this work assignment. Interaction between the contractor and any EPA technical representative(s) designated by the EPA WAM is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this work assignment. The interaction will be technical communication vice technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the PO and the WAM or alternate WAM are the primary representatives of the CO authorized to provide technical direction.

## **WORK ASSIGNMENT CONTRACT OFFICER REPRESENTATIVE (WA-COR) AND ALTERNATE WA-COR**

### **WA-COR:**

Thomas Tracy  
Designated Federal Officer  
Board of Scientific Counselors  
Office of Research and Development  
U.S. Environmental Protection Agency  
Mail Code 8104R  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

202-564-6518

### **Alternate WA-COR:**

Anthony Grimm

Office of Science Policy  
Office of Research and Development  
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202-564-0153

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 4-26				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   04/30/2019 Base                      Option Period Number      4			Title of Work Assignment/SF Site Name BOSC Meeting				
Contractor ICF Incorporated, L.L.C.					Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/01/2017   To   04/30/2019				
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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Contractor WP Dated:				Cost/Fee			LOE:			
Cumulative Approved:				Cost/Fee			LOE:			
Work Assignment Manager Name   Tom Tracy  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number: 202-564-6518			
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Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
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**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 4-26**

---

**TITLE:** Board of Scientific Counselors (BOSC) Meeting / Conference Support

---

**Specify Section & Paragraph SOW:** E. Risk Assessment Support

1. Science Writing, Risk Communication and Training
2. Administration and Technical Support for NCEA Human Health Related Meetings

**PERIOD OF PERFORMANCE:** November 1, 2018 thru April 30, 2019

**1. BACKGROUND**

The primary functions of the BOSC include evaluating ORD's science and engineering research programs, laboratories, and research-management practices, and recommending actions to improve their quality and/or strengthen their relevance to the mission of the EPA. For more information on the BOSC, go to <http://epa.gov/osp/bosc/>. This work assignment is an extension to work performed in the Year 4 Option Period under Work Assignment # 4-26. The work continues from Task 1 through Task 4 during this extension of Year 4 Option Period under Work Assignment 4-26.

**2. PURPOSE**

The purpose of this Work Assignment is to provide: a full range of administrative and logistical support services for the conduct of Federal Advisory Committee meetings, conferences and/or teleconferences related to the Charter of the Office of Research and Development's Board of Scientific Counselors (BOSC); administrative activities required for reports prepared by the BOSC Executive Committee or its Subcommittees and Workgroups; and the full range of administrative support services for assimilating materials collected from extensive candidate searches conducted for either the Executive Committee, or existing or proposed Subcommittee and Workgroups.

The contractor's activities will not require special expertise in matters of science discussed by the Board, but the contractor should possess the practical knowledge, experience, and skills commonly used in facilitating high-level policy meetings.

Meetings of the BOSC Executive Committee, Subcommittees and Workgroups will generally be held on-site at US EPA (either Headquarters or a Laboratory/Center, as appropriate), if space is available, with the approval of the Designated Federal Officer (DFO). Under this work assignment, it is anticipated that contractor support shall be required for approximately three Executive Committee meetings (one is expected to be face-to-face meeting); approximately 5 face-to-face program review subcommittee meetings. In addition, contractor support shall be needed for approximately 10 conference calls (expected to be 2-3 hour calls) in support of the Subcommittee and Workgroup meetings. The EPA WAM will provide the meeting dates via written technical direction.



It is anticipated that approximately one report shall be generated by the BOSC during the timeframe of this work assignment, and that candidate searches requiring contractor support may occur no more than one time during the period.

### **3. STATEMENT OF WORK**

This Statement of Work describes EPA's requirements regarding services to be rendered by the contractor for BOSC meeting and conference support. The contractor shall provide the necessary personnel and resources in the following four areas for the BOSC:

1. Pre-meeting communication and logistical support.
2. On-site technical support during meetings/teleconferences.
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The contractor shall deliver to the EPA WAM any materials not distributed at the meeting or materials left behind by BOSC members within two working days after the meeting.

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#### **5. SCHEDULE OF DELIVERABLES**

<b>Product</b>	<b>Due Date</b>
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## **WORK ASSIGNMENT CONTRACT OFFICER REPRESENTATIVE (WA-COR) AND ALTERNATE WA-COR**

### **WA-COR:**

Thomas Tracy  
Designated Federal Officer  
Board of Scientific Counselors  
Office of Research and Development  
U.S. Environmental Protection Agency  
Mail Code 8104R  
1200 Pennsylvania Avenue, NW  
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202-564-6518

### **Alternate WA-COR:**

Anthony Grimm

Office of Science Policy  
Office of Research and Development  
U.S. Environmental Protection Agency  
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1200 Pennsylvania Avenue, NW  
Washington, DC 20460

202-564-0153

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 4-44				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2018 Base                      Option Period Number    4			Title of Work Assignment/SF Site Name Decontamination Conf.				
Contractor ICF Incorporated, L.L.C.					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From 11/01/2017 To 10/31/2018				
Comments: Support to the 2018 US EPA International Decontamination Research and Development Conference										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> (Max 2)                      Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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Contract Period:		Cost/Fee:				LOE:				
11/01/2013 To 10/31/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee			LOE:			
Cumulative Approved:				Cost/Fee			LOE:			
Work Assignment Manager Name Timothy Boe  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:			
							Phone Number: 919-541-2617			
							FAX Number:			
Project Officer Name Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:			
							Phone Number: 919-541-0207			
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							Phone Number: 513-487-2055			
							FAX Number:			

## PERFORMANCE WORK STATEMENT

CONTRACT NO. EP-C-14-001

WA 4-44

**TITLE:** Support to the 2018 US EPA International Decontamination Research and Development Conference

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**Specify Section & Paragraph SOW:** E2, Risk Assessment Support; Administration and Technical Support for Meetings

**PERIOD OF PERFORMANCE:** *CO award to 9/30/18*

### I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency (hereinafter EPA or Agency) for administrative and technical support to the 2018 US EPA International Decontamination Research and Development Conference, hosted by EPA's National Homeland Security Research Center (NHSRC).

The desired goals of the conference are the following:

- To bring together federal, state, and local researchers, responders, U.S. and international government and private stakeholders in chemical, biological, and radiological (CBR) remediation and recovery preparedness;
- To facilitate the exchange of information on scientific endeavors, including applied research, field demonstrations, guidance and tool development and field applications related to CBR remediation issues;
- To demonstrate the connection between basic or fundamental decontamination research and applied research, as well as applied research and effective field application; and
- To explore challenges faced by regions, states, and locals in response to natural or man-made incidents.

The work assignment has four major components: (1) the preparation and (2) implementation of a three-day conference to take place on May 8-10, 2018, at the EPA RTP campus in North Carolina; (3) the preparation of a post-conference webpage that compiles the abstracts and presentations along with an executive summary of the conference; and (4) identification of future conference venues. This work assignment includes the following major deliverables:

1. Assistance and coordination with a three-day conference as noted in the tasks;
2. Assistance with plenary speaker and up to four other outside participants;
3. Development, implementation, and distribution of conference materials (e.g., call for abstracts, registration, presentations, and conference summary and proceedings);
4. Assistance and coordination with a three-day conference as noted in the tasks;
5. Post-conference website; and
6. Future planning considerations.



## II. BACKGROUND

Since 2005, NHSRC has organized and hosted an international conference on decontamination research and development. Decontamination is one of the critical challenges that the United States and EPA would face in recovering from a major chemical, biological, or radiological incident.

The conference is designed to facilitate presentation, discussion, and further collaboration on research and development focused on an all-hazards approach to cleaning up contaminated buildings (both interior and exterior), infrastructure, and other areas/materials. The conference continues to focus strongly on matters involving chemical, biological, and radiological (CBR) threat agents but also include “all hazards’ elements.

Topics of interest for this conference include:

- **Regional, State, and Local Initiatives:** highlight local priorities, challenges, and science and technology developments related to response and recovery efforts from intentional or accidental environmental incidents;
- **CBR Detection and Decontamination Research:** New research data, or field activities and large scale demonstrations related to the detection and decontamination of biological (including agricultural threat agents and biotoxins), chemical, and radiological threat agents in indoor (in facilities) or outdoor areas/materials; and
- **Cross Cutting Topics:** clean-up levels/risk assessment, exposure assessment, sampling/analysis of threat agents, fate/transport/containment, material compatibility with decontamination processes, tool and guidance development, waste management of threat agent-contaminated materials, water/wastewater decontamination, and systems approach to response and regulatory issues.

Invitees include persons involved in CBR remediation and recovery research, individuals such as EPA On-Scene Coordinators who conduct remediation activities, people involved in setting policy related to CBR decontamination in the U.S. and abroad, as well as individuals from academia and industry.

## III. STATEMENT OF WORK

### Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM, ALT WAM, and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

### Task 2: Work and Staffing Plan

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in administrative and technical support to a conference.

### Task 3: PRE-CONFERENCE PREPARATION

#### Task 3.1. Conference Abstract Collection:

The contractor shall setup a digital platform for receiving abstracts submitted by participants. The Contractor shall receive conference abstracts following the initial call for abstracts by the conference organizers.

The Contractor shall compile received abstract titles and prepare a spreadsheet to facilitate EPA review of abstracts and placement in the conference program following acceptance by EPA of the presentation.

#### Task 3.2. Pre-registering Conference Participants:

The Contractor shall work with the necessary EPA web and IT personnel in developing an EPA based conference registration website (with an emphasis on mobile-friendly). At the very least, the website shall include a pre-registration

page that contains a list of local hotels and other pertinent logistical information. The registration process shall inquire about United States citizenship (citizen or permanent resident status), identification of research area (down selected from prepopulated list of up to 10 topics), selection of preferred presentation mode (oral vs poster presentation), and whether the contact information (name, affiliation, email address) can be made available to (a) only other registrants of the conference or (b) the general public as part of the post-conference report. Upon receipt of a registration request, the Contractor shall determine if the registrant belongs to the list of invitees as provided by the EPA WAM. If not, the Contractor shall contact the WAM on whether to accept or decline the registration. The Contractor shall confirm a successful registration with the registrant. The EPA WAM will inform a registrant if the registration cannot be accepted.

The Contractor shall provide a list of pre-registrants, by way of a spreadsheet or other digital means, 4 weeks prior to the conference, and again beginning each week thereafter until the start of the conference, unless there were no new pre-registrants added during that period.

The Contractor shall secure a block of rooms at a hotel near the EPA RTP Campus at the government rate. The Contractor shall inquire whether transportation to the EPA RTP Campus can be accommodated by the selected hotel. The Contractor shall work closely with the EPA conference logistics planning committee in selecting the conference hotel(s), restaurants, and other networking venues.

**Task 3.3. Other Pre-Meeting Logistical Activities (e.g. Coordination with speakers, securing on-site Audio/Visual, IT support):**

The Contractor shall, when given a list of potential speakers, moderators, key audience members and other audience categories, secure release forms for presentations by all speakers for both upload onto an ftp-like server or online portal for publication on the conference proceedings site, obtain their appropriate power point presentations and organize these presentations in an appropriate manner to be ready to load onto EPA computers at the conference. The Contractor will confirm moderator participation in cooperation with the WAM. The Contractor shall also provide other necessary logistical support for presenters and attendees including directions to the conference and coordination of presentation materials. Streamlining the process of uploading, reviewing, and distributing abstracts and presentations is emphasized.

The Contractor shall coordinate with the EPA AV support personnel in RTP in advance of the conference to ensure that proper AV equipment is available (microphones, laptops and projectors). EPA has secured meeting space at the EPA facilities on the RTP, NC campus. The Contractor shall serve as the lead point of contact to insure the adequate flow of all activities on the days of the conference and coordinate the speakers and overall participation of other representatives. The Contractor shall include arrangements for a webinar version of the conference (one room only).

The Contractor shall be available for on-site registration as necessary, provide any copies of EPA relevant meeting material and allow sufficient space at the entry table for speakers and participants to leave relevant information for pick-up at the time of on-site registration. The Contractor shall coordinate registration near the main meeting room.

**Task 3.4. Digital Conference Resource:**

The Contractor shall work with the necessary EPA web and IT personnel in developing a mobile friendly webpage for publishing conference information. This resource shall include announcements, final conference agenda materials, and proceedings. The Contractor shall provide a list of overall participants and presenters, their contact information, and bios of presenters. The Contractor shall post this information on the conference webpage no later than 15 days before the conference begins. The Contractor shall also prepare a limited number of information packets for distribution during the conference.

**TASK 4: CONFERENCE INVITED SPEAKER TRAVEL**

**Task 4.1. Invited Speaker Travel:**

The Contractor shall coordinate logistics and fund travel for 1 international and up to 4 domestic invitational speakers as determined by the conference agenda planning committee. The Contractor shall anticipate that the speakers will attend the entire conference.

## **TASK 5: DURING-CONFERENCE RESPONSIBILITIES**

### **Task 5.1. Conference Registrations & Logistics:**

The on-site Contractor support shall include manning the registration table, providing participant name tags and conference information packets, providing support for navigating conference website and/or app, provide EPA handouts (as needed basis), and allowing space for other information provided by speakers ahead of time and signing in registrants.

Furthermore, the Contractor shall work with EPA in identifying and implementing attendee engagement activities to include, but not limited to, keywords on nametags, managing RSVPs for networking events, etc.

### **Task 5.2. Conference IT:**

The EPA will provide laptop computers. The Contractor shall coordinate with the WAM to ensure that all presentations are loaded onto EPA computer. The Contractor shall provide technical support during the conference in coordination with the EPA AV support staff and assist in facilitating the Q&A sessions as needed, including mic coordination.

## **TASK 6: POST-CONFERENCE**

### **Task 6.1. Conference Summary:**

The Contractor shall prepare an executive summary (to include pictures, if permitted) and work with the necessary EPA web and IT personnel for publishing. This summary shall include the Keynote Speaker's presentation, pictures, and question and answer session plus highlights from the other sessions.

### **Task 6.2. Conference Proceedings:**

The Contractor shall work with the necessary EPA web and IT personnel in developing a post-conference website that compiles all presentations, abstracts, speaker question and answer sessions, as well as the conference summary developed under Task 6.1. The conference proceedings shall be downloadable and presented in a searchable table. The conference website shall also include the final agenda, a complete list of actual attendees, their contact information to include contact name, affiliation, and contact information (as agreed upon during the registration process), and pictures and videos taken during the conference.

### **Task 6.3. Future Planning Considerations:**

In preparation for the next conference, the Contractor shall assist EPA in identifying and reserving alternate venues in Washington, D.C. The conference space shall be capable of supporting 300 participants with nearby hotel and restaurant venues. The contractor shall deliver a memo containing recommendations for hotels, travel, and other logistical considerations.

## **IV. ANTICIPATED DELIVERABLES**

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software e.g., MS Office 2013 (or later) spreadsheets and documents.

3 days after award of Work Assignment

### **V. DELIVERABLES AND SCHEDULE** Task 1. Initial Conference Call

Task 2. Work, Staffing Plan

20 days after award

Task 3. List of Abstracts

March 1, 2018

List of Registrants

Digital Conference Resource	4 weeks prior to conference and weekly up to conference date
	April 1, 2018
Task 4. List of Invited Speakers	March 15, 2018
Task 6.1 Draft Conference Summary	Within 6 weeks of conference conclusion
Final Conference Summary	Within 10 business days after receipts EPA comments to draft
Task 6.2 Draft Conference Proceedings	Within 3 months of conference conclusion
Final Conference Proceedings	Within 20 business days after receipts EPA comments to draft
Task 6.3 Planning Memo	Within 3 months of conference conclusion

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 4-44								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001								
Contract Number EP-C-14-001	Contract Period 11/01/2018 To 04/30/2019 Base                      Option Period Number      4	Title of Work Assignment/SF Site Name Decontamination Conf.								
Contractor ICF Incorporated, L.L.C.		Specify Section and paragraph of Contract SOW								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From 11/01/2017 To 04/30/2019								
Comments: This amendment is to do a no cost extension from 10/31/18 to 4/30/19 for post-conference reports and preparations for the 2019 conference, both of which are in the existing SOW. All other terms and conditions remain unchanged.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> (Max 2)                      Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
11/01/2018 To 04/30/2019										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee				LOE:		
Cumulative Approved:				Cost/Fee				LOE:		
Work Assignment Manager Name Timothy Boe  _____ (Signature)                      (Date)							Branch/Mail Code:			
							Phone Number: 919-541-2617			
							FAX Number:			
Project Officer Name Melissa Revely-Wilson  _____ (Signature)                      (Date)							Branch/Mail Code:			
							Phone Number: 919-541-0207			
							FAX Number:			
Other Agency Official Name  _____ (Signature)                      (Date)							Branch/Mail Code:			
							Phone Number:			
							FAX Number:			
Contracting Official Name William Yates  _____ (Signature)                      (Date)							Branch/Mail Code:			
							Phone Number: 513-487-2055			
							FAX Number:			

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 4-26				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   10/31/2018 Base                      Option Period Number       4			Title of Work Assignment/SF Site Name BOSC Meeting				
Contractor ICF Incorporated, L.L.C.					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/01/2017   To   10/31/2018				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund         <span>Accounting and Appropriations Data</span> <input checked="" type="checkbox"/> Non-Superfund       </div>										
Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:                      Cost/Fee:                      LOE: 11/01/2013   To   10/31/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee                      LOE:										
Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name   Tom Tracy  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code:			
							Phone Number: 202-564-6518			
							FAX Number:			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code:			
							Phone Number: 919-541-0207			
							FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code:			
							Phone Number:			
							FAX Number:			
Contracting Official Name   William Yates  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code:			
							Phone Number: 513-487-2055			
							FAX Number:			



**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 4-46 extension**

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**TITLE:** Literature search and analysis of available epidemiological data available for human health effects observed due to in utero exposures to environmental pollutants.

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**Specify Section & Paragraph SOW:** Assessment Issues and Documents 1. Human Health Assessment Documents

**PERIOD OF PERFORMANCE:** CO Award thru 4/30/2018

**I. PURPOSE**

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), for conducting literature searches and subsequent analyses of human epidemiological studies that have observed health effects due to in utero exposure to environmental pollutants. The development of project will include the development of literature searches, systematic review (including risk of bias) evidence tables, identification of biomarkers of exposure and analyses of available NHANES data, derivation of points of departure (PODs) for select studies, characterization of the exposure distribution for women of reproductive age, evaluation of mechanistic data to provide insight into possible adverse outcome pathways (AOPs).

**II. BACKGROUND**

The importance of in utero exposures relative to environmental pollutants has resulted in numerous epidemiological studies characterizing the association between this critical time window of exposure and health effects resulting in later life. Based upon a brief literature search, epidemiological studies have characterized relationships between health effects and environmental pollutants including polybrominated diphenyl ether (Chen et al., 2013; Eskenazi, et al., 2013;), polyaromatic hydrocarbons (PAHs; Perera et al., 2012; 2009), arsenic (Graziano et al., 2014; Nadeau et al., 2014; Recio-Vega et al., 2014; Steinmaus et al., 2014), lead (Nye et al., 2014), methylmercury (Yorifuji, et al., 2014; Zeilmaker et al., 2011; Ryan, 2008), perfluorooctanoic acid (Chen et al., 2013;) and organochlorines (Vested et al., 2014; Eskenazi, et al., 2008). Of the many health effects associated with in utero exposures, developmental neurotoxicity appears to result from many environmental pollutants and this brief review indicates there may exist sufficient data for a number of environmental pollutants to focus on the decrements in IQ. However, based upon the initial literature search other endpoints may be selected to compare across environmental pollutants. Current human health assessments for many of the environmental pollutants identified here have yet to fully evaluate effects associated with in utero exposures. A focused effort on specific health effects (i.e., developmental neurotoxicity) across a group of compounds may provide insight and methodologies for future risk assessments. The Work Assignment Manager (WAM) and other EPA internal reviewers will provide technical direction as necessary.

In conducting the literature review, subsequent analyses, and documents characterizing the state of the science and analyses, the Contractor shall follow, as applicable, the following EPA guidance documents:

- A Review of the Reference Dose and Reference Concentration Processes (U.S. EPA, 2002)
- Guidelines for Neurotoxicity Risk Assessment (U.S. EPA, 1998)

- Guidelines for Reproductive Toxicity Risk Assessment (U.S. EPA, 1996)
- Guidelines for Developmental Toxicity Risk Assessment (U.S. EPA, 1991)
- Guidelines for Mutagenicity Risk Assessment (U.S. EPA, 1986)
- Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry (U.S. EPA, 1994)
- Recommendations for and Documentation of Biological Values for Use in Risk Assessment (U.S. EPA, 1988)
- Guidelines for the Health Risk Assessment of Chemical Mixtures (U.S. EPA, 1986)
- Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures (U.S. EPA, 2000)
- A Framework for Assessing Health Risks of Environmental Exposures to Children (U.S. EPA, 2006)

### **III. STATEMENT OF WORK**

#### **A. Objective**

The objective of this Work Assignment (WA) is to provide technical support for the development of analyses and documents characterizing the state of the science on health effects observed in human populations resulting from in utero exposures to environmental pollutants. Specific requirements for the proposed work are provided below and in guidance documents referenced in this Performance Work Statement (PWS).

#### **B. Specific Requirements**

The use of "redline" versions of the documents shall be employed throughout the process. All documents shall be technically edited for format and grammar before being submitted to the EPA Work Assignment Manager (WAM).

#### **Task 1: Establish Communication**

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

#### **Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)**

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Manual C/O 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)"; "EPA Requirements for Quality Assurance

Project Plans (QAVR-5)"; and "Appendix A. Guidance on Quality Assurance Project Plans for Secondary Research Data."

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved.

#### **Task 4: Systematic Review Data Extraction, Development of Summary Figures**

The objective of this task is to generate the data needed to conduct the analyses needed for a systematic review of the available literature for the selected endpoint(s) to determine the most appropriate studies for inclusion in the analysis. This task will be highly dependent upon the available literature and selection of endpoint(s) / health effects to characterize across a group of environmental pollutants from Task 3. The systematic review will be conducted on multiple endpoints / health effects identified in Task 3, but only endpoint(s) with sufficient data to support a robust analysis. Technical direction will be provided by the WAM as to selection of endpoints and priority for conducting the systematic review. The systematic review will be guided by the PECO statements developed in Task 3 and be limited in scope. The protocol for the systematic review (including risk of bias) will be documented prior to evaluating studies. Although protocol development is outlined in Task 4, there will exist overlap with Task 3 which will require partial development of the protocols for completion of Task 3.

EPA will provide technical direction to finalize and define specific health endpoints for analysis. Technical direction will include but not be limited to providing literature search terms for consideration and refinement of the final endpoint definition. Based on the endpoints identified by EPA (i.e. hypospadias, asthma, cognitive effects, and birth outcomes) the Contractor shall screen and characterize the studies identified through the application of the literature search methodology in order complete and/or identify the set of studies to be included in the analysis. At a minimum, eligible studies shall evaluate NHANES chemicals, use a biomarker in their exposure assessments and examine in utero exposures. Lists of additional informative studies may be compiled as needed.

The Contractor shall extract relevant data from the identified set of studies for each of the endpoint groupings. Data shall include but not be limited to the following:

- (1) Measure of effect or association;
- (2) Chemical
- (3) Biomarker
- (4) Outcome
- (5) Covariates considered (e.g. age, sex)
- (6) Dose-response analysis (Yes/No)
- (7) Other study details (e.g. population, comparison, study design, outcome ascertainment)

The Contractor shall assist EPA in efforts to standardize or transform data so that it can be plotted and overlaid with NHANES exposure distribution data (see Task 5).

Specific requirements of this task:

- 4.1 Systematic Review Methods Report: The Contractor shall develop a report summarizing the methods applied in the project overall and in the hypospadias pilot project.
- 4.2 Revise report: In Consultation with EPA, the Contractor shall revise and frame findings from the reports to be suitable for publication in a peer-reviewed journal. The Contractor shall provide any revision(s) to the WAM for review prior to final acceptance. The Contractor shall participate in telephone meetings as needed with EPA staff.

**Deliverables:**

**Systematic Review Methods Report**

**Summary report of systematic review of selected studies (i.e. hypospadias)**

**Revisions to methods report to be suitable for publication in a peer-reviewed journal**

**Assistance with responses to comments from reviewers on the methods paper**

**Revisions to various figures, tables, analyses, or text previously generated under this PWS in order to support additional publications in a peer-reviewed journals**

**Assistance with responses to comments from reviewers on any additional publications**

#### **IV. ANTICIPATED DELIVERABLES**

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [\*(.d), \*.out, \*.opt, \*.ssn]).

## **V. DELIVERABLES AND SCHEDULE**

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	15 days after award
Task 3. Literature Search for Epi Literature from In Utero Exposures	
Task 3.1 – Literature Search and Hazard ID	
• Literature Search Product and Documentation	June 30, 2016
Task 4. Systematic Review	
Task 4.1 – Systematic Review and Dose-Response Analyses	
<ul style="list-style-type: none"> <li>• Revisions to Methods Report (including hypospadias pilot)</li> <li>• Assistance with responses to comments from reviewers on methods paper</li> <li>• Revisions to figures, tables, analyses, or text for additional manuscripts generated from analyses performed under this PWS.</li> <li>• Assistance with responses to comments from reviewers on additional papers</li> </ul>	December 15, 2018
Asthma <ul style="list-style-type: none"> <li>○ Literature Search Result Summary</li> <li>○ List of Studies and Chemicals</li> <li>○ Data Extraction and Standardization</li> <li>○ Summary Plots</li> </ul>	TBD
Cognitive Effects <ul style="list-style-type: none"> <li>○ Literature Search Result Summary</li> <li>○ List of Studies and Chemicals</li> <li>○ Data Extraction and Standardization</li> <li>○ Summary Plots</li> </ul>	TBD
Birth Outcomes <ul style="list-style-type: none"> <li>○ Literature Search Result Summary</li> <li>○ List of Studies and Chemicals</li> <li>○ Data Extraction and Standardization</li> <li>○ Summary Plots</li> </ul>	TBD
Task 5. Efforts Related to Exposure Characterization	
Task 5.1 – Exposure Characterization	
• General Exposure Profiles for Selected Pollutants	June 30, 2016
• Exposure Characterization Publicly Available Biomarker Data	June 30, 2016
Task 6. Efforts related to AOPs	
Task 6.1 – AOP Evaluation and Analyses	
• Summary Report of Available Toxicological and Mechanistic Info for Selected Endpoint(s)	4 weeks from completion of Task 4



<b>Task 7. Characterization of Risk Estimation Methodology and Potential Future Directions</b>	
Task 7.1 – Risk assessment approaches	
Summary Report of Available Mechanistic Info for Selected Endpoint(s)	June 30, 2016
<ul style="list-style-type: none"> <li>Summary report for current and future risk assessment methodologies for specific types of studies</li> </ul>	

Note: All days are calendar days.

## **VI. MANAGEMENT CONTROLS**

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

## **VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

## **VIII. SPECIAL CONDITIONS AND ASSUMPTIONS**

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

## **IX. EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Managers (WAMs):

Andrew Hotchkiss, PhD  
919-541-4164  
[Hotchkiss.Andrew@epamail.epa.gov](mailto:Hotchkiss.Andrew@epamail.epa.gov)

Ellen Kirrane, PhD  
919-541-1340  
[Kirrane.Ellen@epamail.epa.gov](mailto:Kirrane.Ellen@epamail.epa.gov)





## Appendix A

### Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

**FOCUS:** the work not only addresses the area of inquiry under consideration but also contributes to its understanding;

**VERIFY:** the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;

**INTEGRITY:** Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?

**RIGOR:** the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;

**UTILITY:** the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.

**CLARITY:** Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

## DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:

Author(s):

Title:

Study Citation:

Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 4-46								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001								
Contract Number EP-C-14-001	Contract Period   11/01/2013   To   04/30/2019 Base                      Option Period Number      4	Title of Work Assignment/SF Site Name in utero exposures								
Contractor ICF Incorporated, L.L.C.		Specify Section and paragraph of Contract SOW								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From   11/01/2018   To   04/30/2019								
Comments: See PWS also change the period of performance from 10/31/18 to 4/20/2019. All other terms and conditions remain unchanged.										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund         <span>Accounting and Appropriations Data</span> <input checked="" type="checkbox"/> Non-Superfund       </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
11/01/2013 To 04/30/2019										
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Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee				LOE:		
Cumulative Approved:				Cost/Fee				LOE:		
Work Assignment Manager Name   Andrew Hotchkiss							Branch/Mail Code:			
<div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Phone Number: 919-541-4164			
							FAX Number:			
Project Officer Name   Melissa Revely-Wilson							Branch/Mail Code:			
<div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Phone Number: 919-541-0207			
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Other Agency Official Name							Branch/Mail Code:			
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							FAX Number:			
Contracting Official Name   William Yates							Branch/Mail Code:			
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							FAX Number:			

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 4-50				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   10/31/2018 Base                      Option Period Number                      4			Title of Work Assignment/SF Site Name EPA-Eco-Box				
Contractor ICF Incorporated, L.L.C.						Specify Section and paragraph of Contract SOW				
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/01/2017   To   10/31/2018				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund         <span>Accounting and Appropriations Data</span> <input checked="" type="checkbox"/> Non-Superfund       </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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Contract Period:                      Cost/Fee:                      LOE: 11/01/2013   To   10/31/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee                      LOE:										
Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name   Linda Phillips  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 703-347-0366 FAX Number:			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name   William Yates  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:			



**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 4-50**

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**TITLE:** Technical Support for Revisions to EPA-Eco-Box (a toolbox for ecological risk assessors)

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**Specify Section & Paragraph SOW:** III.C.

**PERIOD of PERFORMANCE:** CO approval through 10/31/2017.

**I. PURPOSE.**

The purpose of this work assignment is to obtain technical support services to the US Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Environmental Assessment (NCEA) for revisions to EPA-Eco-Box (a toolbox for ecological risk assessors). This is a continuation of efforts conducted under work assignment 1-50, 2-50, and 3-50 of contract number EP-C-14-001.

**II. BACKGROUND AND OBJECTIVES.**

EPA-Eco-Box is an online toolbox for ecological risk assessors. It was developed by EPA's Office of Research and Development, National Center of Environmental Assessment (NCEA) to serve as a web-based compendium of ecological risk assessment tools. It is comprised of a series of Tool Sets, each containing modules that address ecological risk assessment topics. Toolbox modules contain descriptions of the topics and links to ecological risk assessment resources including databases, models, guidance documents, and other resources for exposure assessors. A search interface allows users to identify resources using keywords or topics. EPA-Eco-Box is expected to be released in Fall 2017. Periodic maintenance of the Toolbox after its release will be necessary to ensure that EPA-Eco-Box content and tool links remain current. Technical assistance will be required for updating EPA-Eco-Box as needed.

**III. STATEMENT OF WORK.**

The contractor shall be responsible for completion of five tasks. A summary of each task is provided below, including the time frame during which the task shall be completed.

**Task 1. The contractor shall establish communication, submit a work plan, and arrange for routine updates for the EPA Contracting Officer's Representative (COR).**

The contractor shall schedule an initial conference call **within 1 week** after the receipt of the work assignment. The call shall include the COR and relevant members of the ICF team.

**Deliverable 1:** The contractor shall arrange a conference call with the COR, **within 1 week after the receipt of the work assignment.**

**Task 2. The contractor shall assist in correcting broken links in EPA-Eco-Box.**

The contractor shall conduct a maximum of 2 comprehensive reviews of the links in EPA-Eco-Box to identify and correct any broken links **at intervals to be designated by the COR in written technical direction.** **Within 2 weeks of receiving technical direction from the COR,** the contractor shall suggest replacement links for broken links and/or links to outdated tools. A record of these changes shall be maintained by the contractor using the tracking spreadsheet maintained under work assignment 3-50 of the contract.

**Deliverable 2a:** The contractor shall conduct a maximum of 2 comprehensive reviews of the links in the Master Tool List **at intervals to be designated by the COR in written technical direction.**

**Deliverable 2b:** The contractor shall provide replacement links for broken links and/or links to outdated tools **within 2 weeks of receiving technical direction from the COR.**

### **Task 3. The contractor shall assist in addressing comments on EPA-Eco-Box.**

The contractor shall assist EPA in addressing comments/questions received on EPA-Eco-Box, as needed. The contractor shall prepare and submit to the COR draft responses **within 1 week after receiving comments/questions from the COR.** For the purpose of preparing the work plan and cost estimate for this work assignment, the contractor shall assume that, if any, only minor comments/questions will be received. The contractor shall also assume that if revisions to the toolbox are needed, they will be minor. The list of comments/questions and their resolution that was maintained under work assignments 3-50 of this contract shall continue to be maintained in order to track revisions made to the Toolbox.

**Deliverable 3:** The contractor shall prepare and submit responses to the comments/questions, and any proposed changes to the toolbox, **within 1 week of being assigned by the COR.**

### **Task 4. The contractor shall assist in updating EPA-Eco-Box content**

Revisions to EPA-Eco-Box may occasionally be needed to reflect updated EPA ecological risk assessment policies or procedures. Based on technical direction from the COR, the contractor shall identify specific areas within EPA-Eco-Box that will require revision and provide suggested changes to the Toolbox. For the purposes of this cost estimate, the contractor shall assume that, if any, only minor revisions will be required, given that the Toolbox is still relatively new. The contractor shall provide the COR with a list of suggested revisions **within 2 weeks of receiving technical direction from the COR regarding the necessary revisions.**

**Deliverable 4:** The contractor shall provide the COR with a detailed list of suggested revisions **within 2 weeks after receiving technical direction from the COR.**

### **Task 5. The contractor shall provide information to update the Master Tool List**

A Master Tool List for EPA-Eco-Box was developed previously under work assignments 1-50, 2-50, and 3-50 of EP-C-14-001. The contractor shall provide the necessary information to revise and update the Master Tool List, as needed, to correct broken links (Task 2), to incorporate any new tools that have been identified from

comments/questions on the Toolbox (see Task 3), and to add tools based on the revision of existing content (Tasks 4). The contractor shall ensure that any new or updated tools have been appropriately assigned to the various Tool Sets, modules, and sub-modules (many of the tools will be applicable in more than one module or sub-module), and that accurate tool descriptions and key words are provided. The contractor shall submit all of the draft information necessary to revise and update the Master Tool List to the COR **within 2 weeks after completing Tasks 2, 3, and 4** for comment by the COR. **Within 1 week after receiving comments from the COR**, the contractor shall submit the final information necessary to update the Master Tool List.

**Deliverable 5a:** The contractor shall submit to the COR draft information necessary to revise and update the Master Tool List **within 2 weeks after completing Tasks 2, 3, and 4**.

**Deliverable 5b:** The contractor shall submit the final information necessary to update the Master Tool List to the COR **within 1 week after the receipt of the COR's comments on Deliverable 5a**.

The contractor shall furnish electronic copies of (or internet links to) any references or other materials obtained in the preparation of the deliverables for this work assignment.

#### **.IV. TIME TABLE.**

<b>Task</b>	<b>Deliverable</b>	<b>Time frame</b>
1a	Establish communication via conference call	Within 1 week after receipt of work assignment
2a	Review Toolbox links	At intervals to be designated by COR
2b	Provide replacement links	Within 2 weeks of receiving technical direction from the COR
3	Prepare responses to issues or topic areas	Within 1 week of being assigned by COR
4	Submit revised content	Within 2 weeks of being assigned by COR
5a	Submit draft information for Master Tool List	Within 2 weeks after completing Tasks 2, 3, and 4
5b	Submit final information for Master Tool List	Within 1 week of COR comments

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.
2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA Project Officer (PO).
3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.
4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

#### **V. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

## **VII. EPA CONTACT INFORMATION.**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the COR.

### **Work Assignment Manager**

Linda Phillips

US EPA (8623P)

National Center for Environmental Assessment

Office of Research and Development

U.S. Environmental Protection Agency

1200 Pennsylvania Ave. NW

Washington, DC 20460

Telephone #: (703) 347-0366

FAX #: (703) 347-8690

Email: [phillips.linda@epa.gov](mailto:phillips.linda@epa.gov)

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 4-50			
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001			
Contract Number EP-C-14-001		Contract Period   11/01/2017   To   10/31/2018 Base                      Option Period Number       4		Title of Work Assignment/SF Site Name EPA-Eco-Box					
Contractor ICF Incorporated, L.L.C.				Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/01/2017   To   10/31/2018			
Comments: This amendment is to add Maureen Johnson as the Alt. COR. All other terms and conditions remain unchanged.									
<input type="checkbox"/> Superfund    Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund									
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)  (Cents)	Site/Project (Max 8)	Cost Org/Code
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Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee:		LOE:					
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Work Plan / Cost Estimate Approvals									
Contractor WP Dated:				Cost/Fee		LOE:			
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Work Assignment Manager Name   Linda Phillips  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>						Branch/Mail Code:			
						Phone Number: 703-347-0366			
						FAX Number:			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>						Branch/Mail Code:			
						Phone Number: 919-541-0207			
						FAX Number:			
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						Phone Number:			
						FAX Number:			
Contracting Official Name   William Yates  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>						Branch/Mail Code:			
						Phone Number: 513-487-2055			
						FAX Number:			

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 4-50				
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Contract Number EP-C-14-001			Contract Period   11/01/2013   To   04/30/2019 Base                      Option Period Number       4			Title of Work Assignment/SF Site Name EPA-Eco-Box				
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Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/01/2017   To   04/30/2019				
Comments:										
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Work Plan / Cost Estimate Approvals										
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Cumulative Approved:				Cost/Fee			LOE:			
Work Assignment Manager Name   Linda Phillips  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 703-347-0366 FAX Number:			
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Contracting Official Name   William Yates  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:			



<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 4-51				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   10/31/2018 Base                      Option Period Number       4			Title of Work Assignment/SF Site Name Meeting Support				
Contractor ICF Incorporated, L.L.C.					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/01/2017   To   10/31/2018				
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Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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Contract Period:		Cost/Fee:			LOE:					
11/01/2013   To   10/31/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee			LOE:			
Cumulative Approved:				Cost/Fee			LOE:			
Work Assignment Manager Name   Thomas O'Farrell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 703-347-8085 FAX Number:			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:			
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Contracting Official Name   William Yates  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:			

## **PERFORMANCE WORK STATEMENT**

**Contract # EP-C-14-001**

**WA 4-51**

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**TITLE:** Meeting Support for Science and Technology Policy Council and Scientific Support Panel Staff and Related Interagency Activities in Support of the EPA Science Advisor

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**NOTE:** This work assignment is a follow-on to work performed in the Year 3 Option Period under Work Assignment # 3-51. The work continues on Tasks 1, 2, 4, and 5 (former Task 3 will not continue this year) during this Year 4 Option Period under Work Assignment 4-51. This PWS describes only Tasks 1-4. Tasks 1-5 from Option Year 3 have been completed.

**Specify Section & Paragraph SOW: E. Risk Assessment Support - Meetings**

**PERIOD OF PERFORMANCE: CO Approval – October 31, 2018**

### **BACKGROUND**

The EPA Science Advisor convenes and chairs the EPA Science and Technology Policy Council (STPC) and Community of Science Staff, which is comprised of senior managers from EPA Offices and Regions. The official STPC representatives are at the Deputy Assistant Administrator and Deputy Regional Administrator level and appropriate level for Offices within the Office of the Administrator. The Science Advisor's priorities for the STPC dovetail with interagency activities, including, but not limited to, the White House Office of Science and Technology Policy (OSTP), National Academies, Government Accountability Office and the Office of Management and Budget. The STPC is supported by a Scientific Support Panel (consisting of Agency Senior Science Advisors) and a small staff within the Office of the Science Advisor (OSA).

### **TASKS**

Establish Communication Within 3 days after award of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The Contractor shall prepare a written work plan describing how the tasks in this PWS will be performed, including a schedule, budget, level of effort, and qualifications of personnel. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.

The Contractor shall also prepare a schedule for deliverables to ensure all materials are properly reviewed, approved, and disseminated.

- 1) The Science Advisor convenes quarterly meetings of the STPC. The Science Advisor may convene additional meetings of the STPC to address specific topics (estimate one special STPC meetings). The EPA Work Assignment (TO) COR will provide meeting logistical information to the contractor in advance. The contractor shall attend the meetings in person, record the meeting and prepare a concise meeting summary report consisting of action items, decisions, and brief summary of discussions. The contractor shall prepare draft and final meeting summary reports based on comments received from EPA WAM, Technical Representative and STPC staff.
- 2) The Scientific Support Panel staff convenes up to six meetings of the Scientific Support Panel each year.

The EPA WAM will provide meeting logistical information to the contractor in advance. The contractor shall attend the meetings by phone, record the meeting and prepare a concise meeting summary report consisting of action items, decisions, and brief summary of discussions. The contractor shall prepare draft and final meeting summary reports based on comments received from EPA WAM, Technical Representative and Community of Science staff.

- 3) The STPC and Scientific Support Panel staff assist ad hoc committees that may be formed at the discretion of the Science Advisor. The contractor shall provide assistance as needed for tasks assigned via Technical Direction from the EPA WAM. Contractor assistance may include: occasional note taking for technical discussions, technical editing of reports, and development of documents, including text, tables, and figures. Estimate support for 2 ad hoc meetings, technical editing of 1 document, less than 150 pages each).
- 4) STPC activities may require support to develop communication and outreach materials for internal and external stakeholders.

### **DELIVERABLES**

- 1) Draft meeting summary reports within two (2) days.
- 2) Provide EPA WAM with electronic link to the audio recording for STPC meetings within 5 days.
- 3) Provide final documents and reports within five (5) days after receipt of EPA comments on draft reports, meeting summary reports, or other task outputs.

### **CONFLICT OF INTEREST**

The contractor shall disclose any conflict of interest regarding this work.

### **ACCEPTANCE CRITERIA**

Deliverables shall be provided to the EPA WAM in accepted Agency format and be of high quality. Deliverables shall be prepared using software compatible with current ORD computer systems. In some cases, the draft document will be sufficient for the purposes of the STPC staff. Deliverables shall be submitted electronically to the EPA WAM via e-mail as well as hard copy (when requested).

### **MANAGEMENT CONTROLS**

Periodic meetings between the EPA and contractor staff are encouraged to discuss any questions that may arise during performance or completion of this TO. At the EPA WAM's discretion, these meetings may occur via teleconference or video conferences. The contractor shall document these meetings and submit copies of this correspondence to the EPA TO.

The EPA WAM may identify one or more EPA technical representatives for this TO. Interaction between the contractor and any EPA technical representative(s) designated by the EPA WAM is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this TO. The interaction will be technical communication vice technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the EPA PO and the EPAWAM or alternate EPA WAM are the sole representatives of the Contracting Officer authorized to provide technical direction.

**WORK ASSIGNMENT COR (WAM):**

Thomas O'Farrell  
Office of Science Advisor  
U.S. EPA (8105R)  
Office of Research and Development  
1200 Pennsylvania Avenue, NW  
Washington, D.C. 20460  
Telephone: (202) 564-8451  
Fax: (202) 564-2070

**ALTERNATE WAM:**

Greg Susanke  
Office of Science Advisor  
U.S. EPA (8105R)  
Office of Research and Development  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Telephone: (202) 564-9945  
Fax: (202) 564-2070

<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> <b>EPA</b>  United States Environmental Protection Agency  Washington, DC 20460  <b>Work Assignment</b> </div> <div style="text-align: right;"> Work Assignment Number  4-51 </div> </div>										
<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001										
Contract Number EP-C-14-001		Contract Period 11/01/2013 To 04/30/2019 Base                      Option Period Number                      4		Title of Work Assignment/SF Site Name Meeting Support						
Contractor ICF Incorporated, L.L.C.			Specify Section and paragraph of Contract SOW							
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval			Period of Performance  From 11/01/2017 To 04/30/2019							
Comments: This amendment is to add an additional hours and to extend the period of performance to 4/30/19. All other terms and conditions remain unchanged. See attached Amended 1 PWS.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
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Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name    Thomas O'Farrell  _____ (Signature)                      (Date)							Branch/Mail Code:			
							Phone Number: 703-347-8085			
							FAX Number:			
Project Officer Name    Melissa Revely-Wilson  _____ (Signature)                      (Date)							Branch/Mail Code:			
							Phone Number: 919-541-0207			
							FAX Number:			
Other Agency Official Name  _____ (Signature)                      (Date)							Branch/Mail Code:			
							Phone Number:			
							FAX Number:			
Contracting Official Name    William M. Yates  _____ (Signature)                      (Date)							Branch/Mail Code:			
							Phone Number: 513-487-2055			
							FAX Number:			

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 4-56				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   10/31/2018 Base                      Option Period Number                      4			Title of Work Assignment/SF Site Name ToxRefDB				
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Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/01/2017   To   10/31/2018				
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Work Plan / Cost Estimate Approvals										
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Cumulative Approved:					Cost/Fee			LOE:		
Work Assignment Manager Name   Sandra Roberts							Branch/Mail Code:			
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Project Officer Name   Melissa Revely-Wilson							Branch/Mail Code:			
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							FAX Number:			



**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 4-56**

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**TITLE:** Technical Support for Curation of Toxicity Reference Database (ToxRefDB)

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**Specify Section & Paragraph SOW:** C. Risk Assessment Data Bases and Computer Tools

**PERIOD of PERFORMANCE:** CO approval through 10/31/2018.

**I. PURPOSE.**

The purpose of this work assignment is to obtain technical support services to the US Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Computational Toxicology (NCCT) to curate available legacy toxicity information on repeat-dose short-term and long-term toxicity studies into the Toxicity Reference Database (ToxRefDB). This work assignment is a follow-on to work performed in the Year 3 Option Period under Work Assignment # 3-56 and possibly a small portion of WA 3-62 (which task is directly related to the work performed in 3-56). The work continues from Task 1 through Task 3 during this Year 4 Option Period under Work Assignment 4-56.

**II. BACKGROUND AND OBJECTIVES.**

The National Center for Computational Toxicology (NCCT) is responsible for developing computational tools and solutions for improving environmental risk assessments and regulatory decisions. NCCT is developing methodologies to characterize chemicals based on known and predicted toxic effects. As a part of this effort, the NCCT's ToxRefDB project (<http://epa.gov/ncct/toxrefdb/>) has compiled thousands of in vivo animal toxicity studies on hundreds of chemicals. ToxRefDB supports NCCT's ToxCast project by providing in vivo data to anchor in vitro and in silico models while also serving as a public reference tool.

**III. STATEMENT OF WORK.**

The Contractor shall provide all technical support within the scope of this Performance Work Statement (PWS). The Contractor shall perform tasks, as specified by individual work assignments issued by the CO. A summary of each task is provided below, including the time frame during which the task shall be completed.

**Task 1. The contractor shall establish communication, submit a work plan, and arrange for routine updates for the EPA Work Assignment Contracting Officer's Representative (WA COR).**

EPA has established a workflow for study extraction that includes submission of batched study files, with 50-100 study files per batch. To facilitate standardized extraction and enable rapid ToxRefDB updates, the EPA has generated Microsoft Access files to match each available study file.

Based on the number of batched study files remaining for extraction, the contractor should provide estimated timelines for return of batches. The contractor and EPA should continue to have 2-4 conference calls per month to discuss priorities for study extraction, questions regarding extraction of some studies, and the status of returning batched, extracted studies.

**Deliverable 1:** The contractor shall maintain regular conference calls to discuss the status of study data extraction.

**Deliverable 2:** The contractor shall provide a timeline for completion of the remaining batched studies for extraction. The timeline should include specific milestone dates.

**Task 2. The contractor shall review the accuracy of the ToxRefDB study file with the associated Microsoft Access study report(s), including capturing the tested and reported status for all observations.**

The ToxRefDB stores roughly 6000 animal toxicology studies in a relational database with controlled vocabularies. Over 1000 chemicals have at least one study in the database. A subset of these studies, roughly 3000, have NOAEL/LOAEL determinations. For each LOAEL, a set of effects were assigned to the LOAEL as being critical. The LOAELs and associated effects have all been entered and tagged in the database previously.

The contractor shall assist EPA in reviewing the LOAELs and associated effects for accuracy in the database to ensure the quality of the following tasks as well as catalog the testing status of all observations (e.g., tested, not tested, not reported). The contractor shall provide a monthly summary of the studies reviewed, any edits performed, and associated comments/issues that have arisen during extraction.

1. Specifically, the contractor will open the source study documents, housed at the EPA, and compare stated NOAEL/LOAEL levels in the documents with levels listed in the Microsoft Access **ToxRefDB outputted file(s)**. The critical effects **and all other treatment-related effects** listed can be compared, reviewed, and updated if necessary in a similar manner. The EPA estimates the review process to take roughly 30 minutes per study, on average. This explanation is the similar work documented in the previous 3-62 WA. This process must happen to successfully perform the said documented task.
2. Additionally, the contractor shall capture the testing status of all study observations provided for in the Microsoft Access **ToxRefDB outputted file(s)**. The EPA estimates the review process to take roughly 30 minutes per study, on average.

**Deliverable 3:** The contractor shall provide a monthly summary of the studies reviewed and any edits performed.

**Task 3. The contractor shall enter quantitative data for all effects.**

The NOAEL/LOAEL determinations and the associated critical effects have been entered and quality controlled (task 2) **as well as all other treatment-related effects** in ToxRefDB. With the goal of performing dose-response modeling (e.g., benchmark dose modeling) to determine more quantitative points of departure, the contractor shall enter the dose-response data (incidence and/or mean +/- standard deviation, and sample size, **as well as any other necessary fields mutually decided**) for each treatment group, including the control group, for all effects tagged **treatment-related and/or critical** in the study.

For example, a study was run at 3 doses plus controls with male and female groups. The NOAEL was established at 10 mg/kg/day and the LOAEL at 100 mg/kg/day based on liver weight gain in males and females, liver hypertrophy in males and females, and thyroid hyperplasia in the males. Additionally, spleen weight increase was observed and deemed treatment-related in the high dose group at 1000 mg/kg/day. With this example, the contractor shall enter the group mean and standard deviation for liver and spleen weights and incidence information for liver hypertrophy and thyroid hyperplasia at each dose level and for the control group(s).

The EPA estimates the primary data extraction to take roughly 2 hours per study, on average, with a secondary review taking 1 hour per study on average.

**Deliverable 4:** The contractor shall provide the COR and technical representative with a monthly summary of the number of studies with completed quantitative data entry as well as any specific comments regarding special cases or anomalies with data entry.

#### **IV. SUMMARY TIME TABLE.**

<b>Task</b>	<b>Deliverable</b>	<b>Time frame</b>
1	Establish communication via conference call	Within 1 week after receipt of work assignment
2	Provide timeline for completion of the remaining batched studies for extraction, including specific milestone dates	Update on status monthly
3	Monthly summary of studies with any edits performed	Monthly
	Provide summary of the number of studies with completed quantitative data entry, as well as any specific comments regarding special cases or anomalies	Monthly

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.
2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA WA COR and technical representative, Dr. Katie Paul-Friedman.
3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.
4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

#### **V. MANAGEMENT CONTROLS**

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
2. The contractor shall comply with other applicable requirements for final work assignments reports stipulated in contract.

#### **VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

1. Formulation of Agency policy
2. Selection of Agency priorities
3. Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the WA COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

## **VII. EPA CONTACT INFORMATION.**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the Work Assignment Contracting Officer's Representative (WA COR).

<b>WA COR</b> Sandra Roberts National Center for Computational Toxicology Office of Research and Development U.S. Environmental Protection Agency 109 T.W. Alexander Dr. (D143-02) RTP, NC 27711 Telephone #: (919) 541-3850 FAX #: (919) 541-1194 Email: Roberts.sandra@epa.gov	<b>Alternate WA COR</b> David Murphy National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency 109 T.W. Alexander Dr. (D143-02) RTP, NC 27711 Telephone #: (919) 541-3835 FAX #: (919) 541-1194 Email: murphy.david@epa.gov
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<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> <h1 style="margin: 0;">EPA</h1> </div> <div> <p>United States Environmental Protection Agency Washington, DC 20460</p> <h2 style="margin: 0;">Work Assignment</h2> </div> </div>		<p>Work Assignment Number 4-56</p> <p><input type="checkbox"/> Other    <input checked="" type="checkbox"/> Amendment Number: 000001</p>																																																																		
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**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 4-56 Amend 1**

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**TITLE:** Technical Support for Curation of Toxicity Reference Database (ToxRefDB)

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**Specify Section & Paragraph SOW:** C. Risk Assessment Data Bases and Computer Tools

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**PERIOD of PERFORMANCE:** CO approval through 10/31/2018.

Additional hours are needed to complete quantitative data extraction for several sub-sources of study data, in particular, the studies from the National Toxicology Program (NTP), the pharmaceutical industry, and, primarily, studies that have been included from the open literature. Originally we had deprioritized the quantitative extraction of data from studies in the open literature because the study designs are quite variable, and would potentially not lend as much quantitative value in the database. However, we have found a number of errors in the original extractions of the open literature present already in the database (found in executing the quality assurance processes we have built and have been using both at EPA and at ICF). As such, we decided that the open literature studies should be quantitatively extracted to not only unlock the quantitative value of these studies, but also to increase the validity of the data coming from sub-sources other than OPP data evaluation records. As the NTP, pharmaceutical, and open literature study designs are fairly variable, these have taken more resources and time to extract than standardized designs like those described in the EPA OPP data evaluation records, thus resulting in overage of funds needed to complete this important work. Critically, ToxRefDB serves as one of the primary sources of legacy *in vivo* toxicity information for building and validating predictive models of hazard and risk, which is a primary task for NCCT in addressing the needs of the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act. As such, finishing this iteration of the database, and the quantitative data extraction that supports it, is of high value to NCCT.

The contractor should assume that it would take the average 2.5- 5 hours per progress study.



**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**

Work Assignment Number

4-111



Other



Amendment Number

Contract Number

EP-C-14-001

Contract Period 11/01/2013 To 10/31/2019

Base

Option Period Number 4

Title of Work Assignment/SF Site Name

Technical Building

Contractor

ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 11/01/2013 To 10/31/2019

Comments



Superfund

## Accounting and Appropriations Data



Non-Superfund

SFO  
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1500-52A

Line	DCN (Max 5)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	Notes	Site/Project (Max 3)	Cost Org/Code
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## Authorized Work Assignment Ceiling

Contract Period

Cost/Fee

LOE

11/01/2013 To 10/31/2019

This Action:

Total:

## Work Plan / Cost Estimate Approvals

Contractor WP Dated

Cost/Fee

LOE

Cumulative Approved

Cost/Fee

LOE

Work Assignment Manager Name Michael Broder

Branch/Mail Code:

Phone Number: 202-544-3997

FAX Number:

(Signature)

(Date)

Project Officer Name KATHA BOVARY-WILSON

Branch/Mail Code:

Phone Number: 202-544-3997

FAX Number:

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Contracting Official Name William Yates

Branch/Mail Code:

Phone Number: 202-544-3997

FAX Number:

(Signature)

(Date)

**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 4-68**

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**TITLE: Technical Editing and Revision Support of Risk Assessment Forum Documents**

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**Specify Section & Paragraph SOW: A. Assessment Issues and Documents**

**PERIOD OF PERFORMANCE:** CO award to 10/31/18

**A. BACKGROUND**

This work assignment is a follow-on to work performed in the Year 3 Option Period under Work Assignment # 3-68. Federal regulatory agencies often rely on risk assessments as a primary component in their decision-making process. To ensure that assessments are conducted in a consistent and transparent manner the Environmental Protection Agency (EPA) develops guidelines, guidance documents and “white papers” to provide a framework for analyzing data. EPA’s Risk Assessment Forum (RAF) is charged with coordinating the development of Agency-wide guidelines and guidance documents that provide that framework. The principal audience for these products are EPA risk assessors and risk managers; however, these documents also provide clarity and transparency to the stakeholders and other interested parties, and are often cited by other regulatory entities.

**B. PURPOSE**

As noted above, guidelines and related products are among the most important products generated by the EPA. These products inform risk assessors how to acquire data and apply it to risk assessments, promote consistency in Agency risk assessments and inform stakeholders and other interested parties of EPA risk assessment policies and practices. As such, these documents need to be written in a clear and concise manner.

The first step in document revision and editing is monitoring discussions among the technical panel to identify changes to the document. Following those meetings, the technical panel will revise the document and the document will be submitted to the Contractor for technical editing.

This work assignment serves as a generic task with the intention that it will cover support for the revision and technical editing of several documents for which technical direction will be issued for each product. The technical direction accompanying each document will contain instructions specific to that product.

**C. KNOWLEDGE AND SKILLS REQUIRED**

Although much of the content has been provided, it is essential that the Contractor possess demonstrated experience in the production of quality EPA guidelines with an appropriate level of expertise in exposure science, human health and ecological risk assessment methods, to adequately critique and edit RAF documents for clarity and consistency, as well as providing grammatical editing. The Contractor shall be experienced with the use of Endnote database software and MS Word 2016. The Contractor shall also be proficient in developing and populating basic databases using MS Access 2016. The Contractor shall be competent in tracking meeting discussions and taking meeting notes. The level of expertise for each task will be commensurate with the technical direction.

## **D. TASKS**

### **Task 1: Establish Communication**

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the COR, workgroup members, and appropriate Contractor staff to clarify outstanding questions and confirm the schedule and specific tasks for the work assignment. Similarly, the Contractor shall initiate communication with the COR within three days of the issuance of any technical direction issued by the COR. The Contractor shall initiate additional communication with the COR should developments arise that will affect the conduct or schedule of the assignment.

### **Task 2: Work Plan and Staffing Plan**

The Contractor shall prepare a Technical Work Plan describing how the work outlined in the technical direction under this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel.

### **Task 3. Tracking Meeting Discussions**

The Contractor shall participate in meetings as stated in the technical direction; take meeting notes on recommended changes to the document; record the changes in the compiled comments from reviewers and incorporate those changes in the document. The Contractor shall update references, links, and hyperlinks consistent with the revisions per technical direction.

### **Task 4. Technical Editing**

The Contractor shall review and edit the document addressing grammatical, syntax, and spelling errors, consistency in the use of terms, formatting and voice in the document with specific attention to the items listed in the technical direction. The technical direction may also include associated activities such as tabulating reviewers' comments on draft documents. As stated in the technical direction, the Contractor shall establish or maintain a database of references/citations in Endnote software. The Contractor shall maintain ongoing communication with the COR to ensure quality and timely completion of the project.

### **Task 5. Compilation of Comments**

As per technical direction, the Contractor shall compile comments received during review of the document and assemble the comments in a format per technical direction. As appropriate and in consultation with the COR, comments of a similar vein shall be consolidated.

### **Task 6. Delivery of the Final Product**

The Contractor may deliver electronic versions (MS Word 2013 or as specified in the technical direction) of the edited document to the COR, alternate COR, and others designated in the technical direction including both clean and marked-up drafts: the latter shall be a revised document presented as a "track changes."

## E. SCHEDULE AND DELIVERABLES

Product	Due Date
<b>Task 1.</b> Initial Conference Call	3 days after award
<b>Task 2.</b> Staffing Plan	Per contract requirements
<b>Task 3.</b> Attend and track meetings, taking notes. The Contractor shall update references, links, and hyperlinks consistent with the revisions per technical directions.	As specified in the technical direction
<b>Task 4.</b> Shall review and edit the document addressing grammatical, syntax, and spelling errors that may exist in the document with specific attention to the items listed in the technical direction laid out in the attachment.	As specified in the technical direction.
<b>Task 5.</b> Shall compile comments received during review of the document.	As specified in the technical direction.
<b>Task 6.</b> Shall deliver an electronic version (MS Word or as directed in the technical direction) of the draft document to the COR, alternate COR, and others designated in the technical direction including each in both clean and marked-up drafts: the latter shall be a revised document presented as a “track changes unless otherwise specified in the technical direction.	As specified in the technical direction.

## F. Acceptance Criteria

Final products shall be produced by the Contractor upon the EPA WA COR’s approval through written technical direction. The Contractor shall provide all materials written as part of these tasks to the EPA WA COR, as per work assignment, in electronic format. Electronic versions shall be in MS Word 2013, PowerPoint 2013 and Excel 2013 computer format unless otherwise specified in the technical direction.

## G. MANAGEMENT CONTROLS:

Periodic meetings between the EPA and Contractor work assignment managers are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WA COR’s discretion, these meetings may occur via teleconference or video conferences. The Contractor shall document these meetings and submit copies of this correspondence to the EPA WA COR.

The EPA WA COR may identify one or more EPA technical representatives for this work assignment. Interaction between the Contractor and any EPA technical representative(s) designated by the EPA WA COR is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this work assignment. The interaction will be technical communication vice technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the EPA PO COR and the EPA WA COR or alternate EPA WA COR are the only representatives of the CO authorized to provide technical direction.

Per the technical direction clause, the CO and PO will be provided with copies of all technical direction.

## H. CONFIDENTIALITY

Some of the information to be edited under this task may be internal information that is not ready for public distribution. The Contractor shall not discuss the contents of the document with anyone not specified as a participant in the document review process or its preparation.

## VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The Contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

### **NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO

### **SPECIAL CONDITIONS AND ASSUMPTIONS**

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

### **EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

#### **Work Assignment Manager (WAM):**

##### **Work Assignment COR**

Michael W. Broder  
Office of Science Advisor  
U.S. EPA (8105-R)  
Office of the Science Advisor  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460  
Telephone: (202) 564-3393  
Fax: (202) 564-2070

##### **Alternate Work Assignment COR:**

Lawrence Martin  
Office of the Science Advisor  
U.S. EPA (8105-R)  
1200 Pennsylvania Ave., NW  
Washington, DC, 20460  
Telephone (202) 564-6497  
Fax: (202) 564-2070

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 4-68				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 04/30/2019			Title of Work Assignment/SF Site Name				
			Base                      Option Period Number                      4			Technical Editing				
Contractor ICF Incorporated, L.L.C.					Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval					Period of Performance  From 11/01/2017 To 04/30/2019					
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> (Max 2)                      Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE:				
11/01/2013 To 04/30/2019										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:					Cost/Fee			LOE:		
Cumulative Approved:					Cost/Fee			LOE:		
Work Assignment Manager Name Michael Broder							Branch/Mail Code:			
							Phone Number: 202-564-3393			
_____ (Signature)                      (Date)							FAX Number:			
Project Officer Name Melissa Revely-Wilson							Branch/Mail Code:			
							Phone Number: 919-541-0207			
_____ (Signature)                      (Date)							FAX Number:			
Other Agency Official Name							Branch/Mail Code:			
							Phone Number:			
_____ (Signature)                      (Date)							FAX Number:			
Contracting Official Name William M. Yates							Branch/Mail Code:			
							Phone Number: 513-487-2055			
_____ (Signature)                      (Date)							FAX Number:			



**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 4-68**

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**TITLE: Technical Editing and Revision Support of Risk Assessment Forum Documents**

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**Specify Section & Paragraph SOW: A. Assessment Issues and Documents**

**PERIOD OF PERFORMANCE:** November 1, 2018 to April 30, 2019

**A. BACKGROUND**

This work assignment is a follow-on to work performed in the Year 3 Option Period under Work Assignment # 3-68. Federal regulatory agencies often rely on risk assessments as a primary component in their decision-making process. To ensure that assessments are conducted in a consistent and transparent manner the Environmental Protection Agency (EPA) develops guidelines, guidance documents and “white papers” to provide a framework for analyzing data. EPA’s Risk Assessment Forum (RAF) is charged with coordinating the development of Agency-wide guidelines and guidance documents that provide that framework. The principal audience for these products are EPA risk assessors and risk managers; however, these documents also provide clarity and transparency to the stakeholders and other interested parties, and are often cited by other regulatory entities.

**B. PURPOSE**

As noted above, guidelines and related products are among the most important products generated by the EPA. These products inform risk assessors how to acquire data and apply it to risk assessments, promote consistency in Agency risk assessments and inform stakeholders and other interested parties of EPA risk assessment policies and practices. As such, these documents need to be written in a clear and concise manner.

The first step in document revision and editing is monitoring discussions among the technical panel to identify changes to the document. Following those meetings, the technical panel will revise the document and the document will be submitted to the Contractor for technical editing.

This work assignment serves as a generic task with the intention that it will cover support for the revision and technical editing of several documents for which technical direction will be issued for each product. The technical direction accompanying each document will contain instructions specific to that product.

**C. KNOWLEDGE AND SKILLS REQUIRED**

Although much of the content has been provided, it is essential that the Contractor possess demonstrated experience in the production of quality EPA guidelines with an appropriate level of expertise in exposure science, human health and ecological risk assessment methods, to adequately critique and edit RAF documents for clarity and consistency, as well as providing grammatical editing. The Contractor shall be experienced with the use of Endnote database software and MS Word 2016. The Contractor shall also be proficient in developing and populating basic databases using MS Access 2016. The Contractor shall be competent in tracking meeting discussions and taking meeting notes. The level of expertise for each task will be commensurate with the technical direction.

## **D. TASKS**

### **Task 1: Establish Communication**

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the COR, workgroup members, and appropriate Contractor staff to clarify outstanding questions and confirm the schedule and specific tasks for the work assignment. Similarly, the Contractor shall initiate communication with the COR within three days of the issuance of any technical direction issued by the COR. The Contractor shall initiate additional communication with the COR should developments arise that will affect the conduct or schedule of the assignment.

### **Task 2: Work Plan and Staffing Plan**

The Contractor shall prepare a Technical Work Plan describing how the work outlined in the technical direction under this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel.

### **Task 3. Tracking Meeting Discussions**

The Contractor shall participate in meetings as stated in the technical direction; take meeting notes on recommended changes to the document; record the changes in the compiled comments from reviewers and incorporate those changes in the document. The Contractor shall update references, links, and hyperlinks consistent with the revisions per technical direction.

### **Task 4. Technical Editing**

The Contractor shall review and edit the document addressing grammatical, syntax, and spelling errors, consistency in the use of terms, formatting and voice in the document with specific attention to the items listed in the technical direction. The technical direction may also include associated activities such as tabulating reviewers' comments on draft documents. As stated in the technical direction, the Contractor shall establish or maintain a database of references/citations in Endnote software. The Contractor shall maintain ongoing communication with the COR to ensure quality and timely completion of the project.

### **Task 5. Compilation of Comments**

As per technical direction, the Contractor shall compile comments received during review of the document and assemble the comments in a format per technical direction. As appropriate and in consultation with the COR, comments of a similar vein shall be consolidated.

### **Task 6. Delivery of the Final Product**

The Contractor may deliver electronic versions (MS Word 2016 or as specified in the technical direction) of the edited document to the COR, alternate COR, and others designated in the technical direction including both clean and marked-up drafts: the latter shall be a revised document presented as a "track changes."

## E. SCHEDULE AND DELIVERABLES

Product	Due Date
<b>Task 1.</b> Initial Conference Call	3 days after award
<b>Task 2.</b> Staffing Plan	Per contract requirements
<b>Task 3.</b> Attend and track meetings, taking notes. The Contractor shall update references, links, and hyperlinks consistent with the revisions per technical directions.	As specified in the technical direction
<b>Task 4.</b> Shall review and edit the document addressing grammatical, syntax, and spelling errors that may exist in the document with specific attention to the items listed in the technical direction laid out in the attachment.	As specified in the technical direction.
<b>Task 5.</b> Shall compile comments received during review of the document.	As specified in the technical direction.
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## F. Acceptance Criteria

Final products shall be produced by the Contractor upon the EPA WA COR’s approval through written technical direction. The Contractor shall provide all materials written as part of these tasks to the EPA WA COR, as per work assignment, in electronic format. Electronic versions shall be in MS Word 2016, PowerPoint 2016 and Excel 2016 computer format unless otherwise specified in the technical direction.

## G. MANAGEMENT CONTROLS:

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### **EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

#### **Work Assignment Manager (WAM):**

##### **Work Assignment COR**

Michael W. Broder  
Office of Science Advisor  
U.S. EPA (8105-R)  
Office of the Science Advisor  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460  
Telephone: (202) 564-3393  
Fax: (202) 564-2070

##### **Alternate Work Assignment COR:**

Lawrence Martin  
Office of the Science Advisor  
U.S. EPA (8105-R)  
1200 Pennsylvania Ave., NW  
Washington, DC, 20460  
Telephone (202) 564-6497  
Fax: (202) 564-2070

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 4-75								
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-14-001	Contract Period   11/01/2013   To   10/31/2018 Base                      Option Period Number      4	Title of Work Assignment/SF Site Name Human Exposure Models								
Contractor ICF Incorporated, L.L.C.		Specify Section and paragraph of Contract SOW								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From   11/01/2017   To   10/31/2018								
Comments: This work assignment is a follow-on to work performed in the Year 3 Option Period under Work Assignment # 3-75. The work continues from Task 1 through Task 4 during this Year 4 Option Period under Work Assignment 4-75.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
11/01/2013   To   10/31/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee				LOE:		
Cumulative Approved:				Cost/Fee				LOE:		
Work Assignment Manager Name   Daniel Vallero							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 919-541-3306			
							FAX Number:			
Project Officer Name   Melissa Revely-Wilson							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 919-541-0207			
							FAX Number:			
Other Agency Official Name							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number:			
							FAX Number:			
Contracting Official Name   William Yates							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 513-487-2055			
							FAX Number:			



**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA – 4-75**

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**NOTE:** This work assignment is a follow-on to work performed in the Year 3 Option Period under Work Assignment # 3-75. The work continues from Task 1 through Task 4 during this Year 4 Option Period under Work Assignment 4-75.

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**TITLE:** Identification and adaptation of human exposure models to improve exposure factors in life cycle analysis applied to products and articles

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**PERIOD OF PERFORMANCE:** 11/1/2017– 10/31, 2018

**Specify Section & Paragraph SOW: (select all that apply)**

A. Assessment Issues and Documents

5. Integrated Science Assessments

B. Risk Assessment Methods Research and Development

F. Information Management

G. Literature Search

H. Physiologically-Based Pharmacokinetic (PBPK) Model Technical Support

**I. PURPOSE**

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) Human Exposure and Atmospheric Sciences Division of the National Exposure Research Laboratory, Office of Research and Development (ORD).

**II. BACKGROUND**

The EPA's Chemical Safety for Sustainability research program has been developing new ways to prioritize the chemicals that are ingredients of products and articles. This prioritization has addressed both the toxicity potential (i.e. ToxCast) and exposure potential (i.e. ExpoCast). Together, these will be the basis for improved methods and approaches for risk prioritization of chemicals as early as possible, with the objective of identifying chemicals before they reach the marketplace or before they are ingredients in products wherein the use would lead to unacceptable exposures. Within modern society, exposure to a wide range of chemicals through our daily habits and routines is ubiquitous and largely unavoidable. The initial focus to estimate exposure to chemicals in products used in microenvironments ( $\mu$ E) necessitates a "systems" model to delineate data needs arising from numerous knowledge bases to integrate product formulations, purchasing and use activities, and human activities.

Evaluating chemical safety and sustainability over the life cycle of chemicals requires drawing upon the various data streams and impact assessment tools from the life cycle assessment (LCA) field, along with improved exposure models that rapidly and reliably characterize exposures and human health impacts of chemicals from direct and indirect exposure pathways, which vary across their full life cycle. LCA has proven to be a valuable tool for systematically comparing processes and products; however, exposure assessment has almost exclusively been devoted to far-field scenarios. Integration of human exposure modeling of near-field scenarios into LCA will require bridging the scientific and technical gaps that currently prevent the harmonious use of the best available methods and tools from both fields. A critical linkage is the development of a modeling system



that makes use of existing stochastic and mechanistic human exposure models and will readily link to inputs and tools from the front-end life cycle inventory (LCI) and LCA modules; especially by enhancing the exposure factor in the calculation of the human health characterization factor.

The human exposure modeling elements of the overall research project will include the evaluation of existing model systems and appropriate adaptation of models to life cycle stages. The following life cycle stages are of particular interest in this effort, in order of priority:

- Residential/general population product use (near field exposure pathways)
- Occupational (professional) product use (near-field exposure pathways)
- Product end-of-life (recycling, reuse, disposal for near- and far-field exposure pathways)
- Product manufacturing (far-field and near-field exposure pathways)
- Chemical manufacturing (far-field and near-field exposure pathways)

Initial research efforts will focus on adapting and integrating near-field residential and general population exposure models into the life cycle framework, and extension of the models to near-field occupational (professional) product use. Evaluation, selection, and adaptation of end-of-life and occupational manufacturing models and modeling approaches is envisioned as a longer-term goal of this effort. Potential collaborations with NIOSH or other relevant organizations for occupational manufacturing exposure modeling will be explored.

The key expectation of this research is more reliable and better human health characterization factors (CFs) through enhancement of exposure metrics within the CF calculation. For residential (and professional) product use, the research builds directly upon recent advances in exposure-based chemical prioritization, ExpoCast, and SHEDS-HT (Stochastic Human Exposure and Dose Simulation, High-Throughput model), and will complement the CSS Rapid Exposure & Dosimetry Project. In particular, the research will leverage the knowledge gained through application of SHEDS-HT to provide higher-throughput estimates of exposure to chemicals in consumer products and articles, based on product chemical function and composition databases (e.g., CPcat and CPCPdb, respectively). The LCI and LCA approaches will benefit from evaluation tools for sustainable manufacturing of chemicals (e.g., GREENSCOPE) for providing specific information at a sub-process level for LCI generation.

Over the FY15-16 time period, SHEDS-HT will be adapted for application in a life cycle inventory and assessment framework. This includes improved time-location-activity diary and dietary algorithms and modification of SHEDS-HT modules to support additional pertinent near- and far-field exposure scenarios. In the longer time frame, near-field model results will be combined with information from other models for chemical/product manufacturing, use and disposal and fate and transport. Moreover, the human exposure modeling system will be developed to be flexible enough to accommodate the LCI and other LCA inputs, scenarios or processes. The project will also include various means of incorporating exposure information into characterization factors, e.g. adaptation of intake fractions, especially the product intake fraction (PiF), which can be combined with toxicity factors, e.g. ToxCast activity concentrations.

Scenario development is an important part of this effort and will be used to define and guide human exposure modeling system development. The system will represent far-field and near-field exposure scenarios. Existing models, especially USEtox, show promise in informing far-field aspects of each life cycle, including the end-of-life outputs. Likewise, SHEDS-HT may be a starting point for near-field models, beginning with residential product and article use and possible adaptation to professional product use. However, other models may be considered and adapted as appropriate. As such, literature reviews will be conducted to determine the relevance and quality of models and databases available, especially for the non-residential scenarios and for end-of-life aspects of these and other LCA stages.

In addition, to simulate different exposure and dose scenarios for chemicals across life-cycle stages, it is important also to consider the differences in the physiologic and pharmacokinetic factors for effected individuals at various life-stages. PBPK models have the capability to incorporate these physiological (e.g., body weight, fat percentage) and pharmacokinetic (e.g., metabolism rate, enzyme levels) variations in a study population. We plan to link probabilistic models of inter-individual variation in exposure and dosimetry using a modular exposure-to-dose approach to investigate the internal doses throughout the life-cycle. At this time it remains unknown whether this can be accomplished through a simple adaptation of an existing algorithm or will require development of a de novo approach. For modeling these linkages and doses, initially we will consider selecting chemicals such as flame retardants or other SVOCs in building materials in a relevant PBPK model for the human exposure modeling system. In particular, we may utilize the GastroPlus software tool and other PBPK related information from internal and external EPA collaborators during the development of the task-specific PBPK models. The goal of the PBPK modeling is to provide more rapid dose estimates across wider ranges of chemical space using widely available chemical and physiological parameters for relevant populations, life cycle stages, and time frames.

An overall goal of the research supported in part by this work assignment is an initial user interface to allow beta testing of a full modeling framework by the potential stakeholders. The model sensitivities and uncertainties will be assessed for each integrated modeling framework. Finally, several forms of model evaluation activities will be performed to ascertain the confidence in the model predictions. Individual modules of the modeling system can be evaluated independently (e.g., scenario definitions, emissions, concentrations, exposures), and overall model performance of the system can be evaluated methodically using biomonitoring data that is currently available (e.g., NHANES) or yet to be collected (e.g., by NIEHS/EPA Sister's Study Pilot project, Duke University's anticipated NIEHS-sponsored SVOC exposure and obesogens project). The biomarker data from such sources will be analyzed either directly or interpreted via reverse toxicokinetics (RTK) semi-empirical modeling methods.

This research project integrates emerging scientific information and tools from the LCA and chemical exposure and dose modeling areas. In particular, the integrated LCA/Exposure Modeling framework will provide the capability to rapidly assess environmental and human exposures to many chemicals and products over the life cycle of chemicals, to support the sustainability goals of CSS and other ORD integrated trans-disciplinary research areas. After environmental and human exposure assessments, the user will be able to identify the main life cycle stages that are influencing the evaluation results. The exposure and dose modeling tools will allow more rapid, flexible and reliable prediction of human exposures and doses for chemicals of interest to CSS within an enhanced LCA framework. The LCA exposure tool will be modular, which will facilitate further integration with ecological and hazard databases by separating inputs, model algorithms, and outputs of variability, sensitivity and uncertainty associated with the predictions.

### **III. STATEMENT OF WORK**

#### **Task 1: Human Behavior Components of Human Exposure Model (HEM)**

Recent research efforts at the EPA have focused on the modeling of human activity and behavior patterns, specifically with respect to behaviors which dictate the use of consumer products, using agent based modeling (ABM) methods. Under the direction of the WA-COR, the Contractor will take existing Python code which shows proof of concept of this method, and develop working R code which implements the method (i.e., the use of ABM to model human behaviors), and creates the independent module to be used in the HEM software to model human behavior.

**Deliverable:** ABM/Human behavior working module (i.e., R code), and appropriate documentation.

## **Task 2: Creation of Longitudinal Exposure Algorithms for HEM**

The HEM must have the capability to model longitudinal exposures via different pathway and routes. To this end, the contractor will develop and implement a longitudinal exposure module. This module will use as its basis the exposure scenario algorithm functions in SHEDS-HT, and take as inputs longitudinal patterns of consumer product use for individuals. The Contractor will develop a proposed approach after receiving initial technical guidance from the WA-COR. The proposed approach will include methods for addressing design issues identified by the WA-COR, including but not limited to implementing the SHEDS-HT fugacity model in a longitudinal manner, storing of longitudinal media concentrations, handling of carry-over exposures, handling of dermal removal process, and tracking of dermal loadings and pathway-specific exposures. The WA-COR will approve the proposed approach, upon which the Contractor will implement the method in R Code and complete a final memo describing the approach and code.

**Deliverable:** Memo describing proposed approach, resulting model code, and report of the results of model performance evaluation.

## **Task 3: Support for HEM**

Throughout development of the HEM model, various support will be needed in the development of individual modules. Support can be defined as (but not limited to): acquisition of additional data to be input into the CPDat database, refinements of the CPDat R package, assistance with IT issues related to making modules available as web-based tools, and writing code to create the control file/management module which will allow for interaction of all modules with each other.

**Deliverable 1:** Memo conveying the refinements and applications of CPDat R package, including the use of the composition tool database developed during Option 2. The report will also document how well the modules will have been integrated and any problems encountered during the integration.

**Deliverable 2:** Report describing proposed approach and resulting model code, and reporting the results of CPDat R package data and model quality evaluations.

## **Task 4: Additional Modules**

The HEM model is being created for application in a life cycle inventory and assessment framework. As such, the model will incorporate modules related to a variety of potential exposure pathways, including occupational exposures, end-of-life exposures, recycling exposures, and far-field exposures. Under the direction of the WA-COR, the Contractor will develop modules to support these additional exposure pathways.

**Deliverable:** Memo describing proposed approach and resulting model code, and reporting the results of model performance evaluation.

## **IV. ANTICIPATED DELIVERABLES**

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (likely to be Word, R, and Excel).



## **V. DELIVERABLES AND SCHEDULE**

<b>Task 1.</b> Working model, code and documentation:	March 30, 2017
EPA Comments	21 work days after receipt of model.
Completed task	14 work days after receiving EPA comments.
<b>Task 2.</b> Memo conveying proposed approach:	February 28, 2017
EPA Response and recommendations memo	21 work days after receipt of memo
Completed task	21 work days after receiving EPA comments
<b>Task 3.</b> Memo conveying CPDat R package	July 31, 2017
EPA Comments	14 work days after receipt of memo.
Completed task	14 work days after receiving EPA comments
CPDat R report	September 10, 2017
EPA Comments	7 work days after receipt of ....
Completed task	5 work days after receiving EPA comments
<b>Task 4.</b>	
Memo describing proposed approach	21 work days after receipt of initial technical direction from WA-COR
Draft Model Code for generating longitudinal exposures	2 months after acceptance of proposed approach by WA-COR
Final Model code and documentation, including results of code testing	1 month after acceptance of draft model code

## **VI. MANAGEMENT CONTROLS**

1. All deliverables shall be reviewed for conformance to the requirements of this WA before being approved as final.
2. The Contractor shall comply with other applicable requirements for final WA reports stipulated in contract.

## **VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

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- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

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## **VIII. SPECIAL CONDITIONS AND ASSUMPTIONS**

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## **IX. EPA CONTACT INFORMATION**

Contracting Officer Representative: Daniel A. Vallero, PhD, NERL/HEASD, [vallero.daniel@epa.gov](mailto:vallero.daniel@epa.gov), 919-541-3306

Alternate COR: Peter P. Egeghy, PhD, NERL/HEASD, [egeghy.peter@epa.gov](mailto:egeghy.peter@epa.gov), 919-541-4103

## Appendix A

### Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

**FOCUS:** the work not only addresses the area of inquiry under consideration but also contributes to its understanding;

**VERIFY:** the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;

**INTEGRITY:** Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?

**RIGOR:** the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;

**UTILITY:** the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.

**CLARITY:** Is it written clearly and appropriately for the nature of the study?



<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 4-75								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001								
Contract Number EP-C-14-001	Contract Period   11/01/2013   To   10/31/2018 Base                      Option Period Number      4	Title of Work Assignment/SF Site Name Human exposure models								
Contractor ICF Incorporated, L.L.C.		Specify Section and paragraph of Contract SOW								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From   11/01/2017   To   10/31/2018								
Comments: The contractor will assist in writing programming code and support QA/QC of the SAS code for SHEDS-Multimedia (SHEDS-MM) as revised and updated to support the Office of Water's revision of the Lead and Copper Rule										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
11/01/2013   To   10/31/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee				LOE:		
Cumulative Approved:				Cost/Fee				LOE:		
Work Assignment Manager Name   Daniel Vallero  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number: 919-541-3306			
							FAX Number:			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number: 919-541-0207			
							FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number:			
							FAX Number:			
Contracting Official Name   William Yates  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number: 513-487-2055			
							FAX Number:			

**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA – 4-75 Increment**

---

**NOTE: This is an increment to Task 4 during this Year 4 Option Period under Work Assignment 4-75. The new work is highlighted below.**

---

**TITLE: Identification and adaptation of human exposure models to improve exposure factors in life cycle analysis applied to products and articles**

---

**PERIOD OF PERFORMANCE:** 11/1/2017– 10/31, 2018

**Specify Section & Paragraph SOW: (select all that apply)**

A. Assessment Issues and Documents

5. Integrated Science Assessments

B. Risk Assessment Methods Research and Development

F. Information Management

G. Literature Search

H. Physiologically-Based Pharmacokinetic (PBPK) Model Technical Support

**I. PURPOSE**

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) Human Exposure and Atmospheric Sciences Division of the National Exposure Research Laboratory, Office of Research and Development (ORD).

**II. BACKGROUND**

The EPA's Chemical Safety for Sustainability research program has been developing new ways to prioritize the chemicals that are ingredients of products and articles. This prioritization has addressed both the toxicity potential (i.e. ToxCast) and exposure potential (i.e. ExpoCast). Together, these will be the basis for improved methods and approaches for risk prioritization of chemicals as early as possible, with the objective of identifying chemicals before they reach the marketplace or before they are ingredients in products wherein the use would lead to unacceptable exposures. Within modern society, exposure to a wide range of chemicals through our daily habits and routines is ubiquitous and largely unavoidable. The initial focus to estimate exposure to chemicals in products used in microenvironments ( $\mu$ E) necessitates a "systems" model to delineate data needs arising from numerous knowledge bases to integrate product formulations, purchasing and use activities, and human activities.

Evaluating chemical safety and sustainability over the life cycle of chemicals requires drawing upon the various data streams and impact assessment tools from the life cycle assessment (LCA) field, along with improved exposure models that rapidly and reliably characterize exposures and human health impacts of chemicals from direct and indirect exposure pathways, which vary across their full life cycle. LCA has proven to be a valuable tool for systematically comparing processes and products; however, exposure assessment has almost exclusively been devoted to far-field scenarios. Integration of human exposure modeling of near-field scenarios into LCA will require bridging the scientific and technical gaps that currently prevent the harmonious use of the best available methods and tools from both fields. A critical linkage is the development of a modeling system that makes use of existing stochastic and mechanistic human exposure models and will readily link to inputs

and tools from the front-end life cycle inventory (LCI) and LCA modules; especially by enhancing the exposure factor in the calculation of the human health characterization factor.

The human exposure modeling elements of the overall research project will include the evaluation of existing model systems and appropriate adaptation of models to life cycle stages. The following life cycle stages are of particular interest in this effort, in order of priority:

- Residential/general population product use (near field exposure pathways)
- Occupational (professional) product use (near-field exposure pathways)
- Product end-of-life (recycling, reuse, disposal for near- and far-field exposure pathways)
- Product manufacturing (far-field and near-field exposure pathways)
- Chemical manufacturing (far-field and near-field exposure pathways)

Initial research efforts will focus on adapting and integrating near-field residential and general population exposure models into the life cycle framework, and extension of the models to near-field occupational (professional) product use. Evaluation, selection, and adaptation of end-of-life and occupational manufacturing models and modeling approaches is envisioned as a longer-term goal of this effort. Potential collaborations with NIOSH or other relevant organizations for occupational manufacturing exposure modeling will be explored.

The key expectation of this research is more reliable and better human health characterization factors (CFs) through enhancement of exposure metrics within the CF calculation. For residential (and professional) product use, the research builds directly upon recent advances in exposure-based chemical prioritization, ExpoCast, and SHEDS-HT (Stochastic Human Exposure and Dose Simulation, High-Throughput model), and will complement the CSS Rapid Exposure & Dosimetry Project. In particular, the research will leverage the knowledge gained through application of SHEDS-HT to provide higher-throughput estimates of exposure to chemicals in consumer products and articles, based on product chemical function and composition databases (e.g., CPcat and CPCPdb, respectively). The LCI and LCA approaches will benefit from evaluation tools for sustainable manufacturing of chemicals (e.g., GREENSCOPE) for providing specific information at a sub-process level for LCI generation.

Over the FY15-16 time period, SHEDS-HT will be adapted for application in a life cycle inventory and assessment framework. This includes improved time-location-activity diary and dietary algorithms and modification of SHEDS-HT modules to support additional pertinent near- and far-field exposure scenarios. In the longer time frame, near-field model results will be combined with information from other models for chemical/product manufacturing, use and disposal and fate and transport. Moreover, the human exposure modeling system will be developed to be flexible enough to accommodate the LCI and other LCA inputs, scenarios or processes. The project will also include various means of incorporating exposure information into characterization factors, e.g. adaptation of intake fractions, especially the product intake fraction (PiF), which can be combined with toxicity factors, e.g. ToxCast activity concentrations.

Scenario development is an important part of this effort and will be used to define and guide human exposure modeling system development. The system will represent far-field and near-field exposure scenarios. Existing models, especially USEtox, show promise in informing far-field aspects of each life cycle, including the end-of-life outputs. Likewise, SHEDS-HT may be a starting point for near-field models, beginning with residential product and article use and possible adaptation to professional product use. However, other models may be considered and adapted as appropriate. As such, literature reviews will be conducted to determine the relevance and quality of models and databases available, especially for the non-residential scenarios and for end-of-life aspects of these and other LCA stages.

In addition, to simulate different exposure and dose scenarios for chemicals across life-cycle stages, it is important also to consider the differences in the physiologic and pharmacokinetic factors for effected individuals at various life-stages. PBPK models have the capability to incorporate these physiological (e.g., body weight, fat percentage) and pharmacokinetic (e.g., metabolism rate, enzyme levels) variations in a study population. We plan to link probabilistic models of inter-individual variation in exposure and dosimetry using a modular exposure-to-dose approach to investigate the internal doses throughout the life-cycle. At this time it remains unknown whether this can be accomplished through a simple adaptation of an existing algorithm or will require development of a de novo approach. For modeling these linkages and doses, initially we will consider selecting chemicals such as flame retardants or other SVOCs in building materials in a relevant PBPK model for the human exposure modeling system. In particular, we may utilize the GastroPlus software tool and other PBPK related information from internal and external EPA collaborators during the development of the task-specific PBPK models. The goal of the PBPK modeling is to provide more rapid dose estimates across wider ranges of chemical space using widely available chemical and physiological parameters for relevant populations, life cycle stages, and time frames.

An overall goal of the research supported in part by this work assignment is an initial user interface to allow beta testing of a full modeling framework by the potential stakeholders. The model sensitivities and uncertainties will be assessed for each integrated modeling framework. Finally, several forms of model evaluation activities will be performed to ascertain the confidence in the model predictions. Individual modules of the modeling system can be evaluated independently (e.g., scenario definitions, emissions, concentrations, exposures), and overall model performance of the system can be evaluated methodically using biomonitoring data that is currently available (e.g., NHANES) or yet to be collected (e.g., by NIEHS/EPA Sister's Study Pilot project, Duke University's anticipated NIEHS-sponsored SVOC exposure and obesogens project). The biomarker data from such sources will be analyzed either directly or interpreted via reverse toxicokinetics (RTK) semi-empirical modeling methods.

This research project integrates emerging scientific information and tools from the LCA and chemical exposure and dose modeling areas. In particular, the integrated LCA/Exposure Modeling framework will provide the capability to rapidly assess environmental and human exposures to many chemicals and products over the life cycle of chemicals, to support the sustainability goals of CSS and other ORD integrated trans-disciplinary research areas. After environmental and human exposure assessments, the user will be able to identify the main life cycle stages that are influencing the evaluation results. The exposure and dose modeling tools will allow more rapid, flexible and reliable prediction of human exposures and doses for chemicals of interest to CSS within an enhanced LCA framework. The LCA exposure tool will be modular, which will facilitate further integration with ecological and hazard databases by separating inputs, model algorithms, and outputs of variability, sensitivity and uncertainty associated with the predictions.

### **III. STATEMENT OF WORK**

#### **Task 1: Human Behavior Components of Human Exposure Model (HEM)**

Recent research efforts at the EPA have focused on the modeling of human activity and behavior patterns, specifically with respect to behaviors which dictate the use of consumer products, using agent based modeling (ABM) methods. Under the direction of the WA-COR, the Contractor will take existing Python code which shows proof of concept of this method, and develop working R code which implements the method (i.e., the use of ABM to model human behaviors), and creates the independent module to be used in the HEM software to model human behavior.

**Deliverable:** ABM/Human behavior working module (i.e., R code), and appropriate documentation.



## **Task 2: Creation of Longitudinal Exposure Algorithms for HEM**

The HEM must have the capability to model longitudinal exposures via different pathway and routes. To this end, the contractor will develop and implement a longitudinal exposure module. This module will use as its basis the exposure scenario algorithm functions in SHEDS-HT, and take as inputs longitudinal patterns of consumer product use for individuals. The Contractor will develop a proposed approach after receiving initial technical guidance from the WA-COR. The proposed approach will include methods for addressing design issues identified by the WA-COR, including but not limited to implementing the SHEDS-HT fugacity model in a longitudinal manner, storing of longitudinal media concentrations, handling of carry-over exposures, handling of dermal removal process, and tracking of dermal loadings and pathway-specific exposures. The WA-COR will approve the proposed approach, upon which the Contractor will implement the method in R Code and complete a final memo describing the approach and code.

**Deliverable:** Memo describing proposed approach, resulting model code, and report of the results of model performance evaluation.

## **Task 3: Support for HEM**

Throughout development of the HEM model, various support will be needed in the development of individual modules. Support can be defined as (but not limited to): acquisition of additional data to be input into the CPDat database, refinements of the CPDat R package, assistance with IT issues related to making modules available as web-based tools, and writing code to create the control file/management module which will allow for interaction of all modules with each other.

**Deliverable 1:** Memo conveying the refinements and applications of CPDat R package, including the use of the composition tool database developed during Option 2. The report will also document how well the modules will have been integrated and any problems encountered during the integration.

**Deliverable 2:** Report describing proposed approach and resulting model code, and reporting the results of CPDat R package data and model quality evaluations.

## **Task 4: Additional Modules**

The HEM model is being created for application in a life cycle inventory and assessment framework. As such, the model will incorporate modules related to a variety of potential exposure pathways, including occupational exposures, end-of-life exposures, recycling exposures, and far-field exposures. Under the direction of the WA-COR, the Contractor will develop modules to support these additional exposure pathways.

In addition, the contractor will assist in writing programming code and support QA/QC of the SAS code for SHEDS-Multimedia (SHEDS-MM) as revised and updated to support the Office of Water's revision of the Lead and Copper Rule. This includes:

- 1) SHEDS-MM modification and programming and QA/QC-related activities;
- 2) Conduct QA/QC on input data, SAS codes and outputs;
- 3) SAS programing support for exposure modeling and data analyses

The SHEDS-MM work should be limited to:

- 1) 1) 4 meeting totaling 5 hours
- 2) 2) Modifying longitudinal assembling macro in SHEDS-MM

- 3) 3) Help with SAS code with length about 500 lines
- 4) 4) Checking 5-10 key SAS programs with total length of about 10000 lines (QA/QC).

**Deliverable:** Memo describing proposed approach and resulting model code, and reporting the results of model performance evaluation.

2-3-page report on the SHEDS-MM QA/QC.

#### **IV. ANTICIPATED DELIVERABLES**

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (likely to be Word, R, and Excel).

#### **V. DELIVERABLES AND SCHEDULE**

<b>Task 1.</b> Working model, code and documentation:	March 30, 2017
EPA Comments	21 work days after receipt of model.
Completed task	14 work days after receiving EPA comments.
<b>Task 2.</b> Memo conveying proposed approach:	February 28, 2017
EPA Response and recommendations memo	21 work days after receipt of memo
Completed task	21 work days after receiving EPA comments
<b>Task 3.</b> Memo conveying CPDat R package	July 31, 2017
EPA Comments	14 work days after receipt of memo.
Completed task	14 work days after receiving EPA comments
CPDat R report	September 10, 2017
EPA Comments	7 work days after receipt of ....
Completed task	5 work days after receiving EPA comments
<b>Task 4.</b>	
Memo describing proposed approach	21 work days after receipt of initial technical direction from WA-COR
Draft Model Code for generating longitudinal exposures	2 months after acceptance of proposed approach by WA-COR
Final Model code and documentation, including results of code testing	1 month after acceptance of draft model code
2-3 page report on the SHEDS-MM QA/QC.	2 months after acceptance of incremental work plan.

#### **VI. MANAGEMENT CONTROLS**



1. All deliverables shall be reviewed for conformance to the requirements of this WA before being approved as final.
2. The Contractor shall comply with other applicable requirements for final WA reports stipulated in contract.

## **VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The Contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

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<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 4-75								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000002								
Contract Number EP-C-14-001	Contract Period   11/01/2017   To   10/31/2018 Base                      Option Period Number      4	Title of Work Assignment/SF Site Name Human Exposure Models								
Contractor ICF Incorporated, L.L.C.		Specify Section and paragraph of Contract SOW								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From   11/01/2017   To   10/31/2018								
Comments: This work assignment's deliverables consist of large datasets and files that exceed transmission limits via email. Therefore, the contractor should obtain a portable data storage device that can hold up to 3 terabytes of data. The device should be USB 3-compatible and encrypted. The cost should not exceed \$300.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
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Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
11/01/2017   To   10/31/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee				LOE:		
Cumulative Approved:				Cost/Fee				LOE:		
Work Assignment Manager Name   Daniel Vallero							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 919-541-3306			
							FAX Number:			
Project Officer Name   Melissa Revely-Wilson							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 919-541-0207			
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Other Agency Official Name							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number:			
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**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA – 4-75 Increment**

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---

**PERIOD OF PERFORMANCE:** 11/1/2017– 10/31, 2018

**Specify Section & Paragraph SOW: (select all that apply)**

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Initial research efforts will focus on adapting and integrating near-field residential and general population exposure models into the life cycle framework, and extension of the models to near-field occupational (professional) product use. Evaluation, selection, and adaptation of end-of-life and occupational manufacturing models and modeling approaches is envisioned as a longer-term goal of this effort. Potential collaborations with NIOSH or other relevant organizations for occupational manufacturing exposure modeling will be explored.

The key expectation of this research is more reliable and better human health characterization factors (CFs) through enhancement of exposure metrics within the CF calculation. For residential (and professional) product use, the research builds directly upon recent advances in exposure-based chemical prioritization, ExpoCast, and SHEDS-HT (Stochastic Human Exposure and Dose Simulation, High-Throughput model), and will complement the CSS Rapid Exposure & Dosimetry Project. In particular, the research will leverage the knowledge gained through application of SHEDS-HT to provide higher-throughput estimates of exposure to chemicals in consumer products and articles, based on product chemical function and composition databases (e.g., CPcat and CPCPdb, respectively). The LCI and LCA approaches will benefit from evaluation tools for sustainable manufacturing of chemicals (e.g., GREENSCOPE) for providing specific information at a sub-process level for LCI generation.

Over the FY15-16 time period, SHEDS-HT will be adapted for application in a life cycle inventory and assessment framework. This includes improved time-location-activity diary and dietary algorithms and modification of SHEDS-HT modules to support additional pertinent near- and far-field exposure scenarios. In the longer time frame, near-field model results will be combined with information from other models for chemical/product manufacturing, use and disposal and fate and transport. Moreover, the human exposure modeling system will be developed to be flexible enough to accommodate the LCI and other LCA inputs, scenarios or processes. The project will also include various means of incorporating exposure information into characterization factors, e.g. adaptation of intake fractions, especially the product intake fraction (PiF), which can be combined with toxicity factors, e.g. ToxCast activity concentrations.

Scenario development is an important part of this effort and will be used to define and guide human exposure modeling system development. The system will represent far-field and near-field exposure scenarios. Existing models, especially USEtox, show promise in informing far-field aspects of each life cycle, including the end-of-life outputs. Likewise, SHEDS-HT may be a starting point for near-field models, beginning with residential product and article use and possible adaptation to professional product use. However, other models may be considered and adapted as appropriate. As such, literature reviews will be conducted to determine the relevance and quality of models and databases available, especially for the non-residential scenarios and for end-of-life aspects of these and other LCA stages.



In addition, to simulate different exposure and dose scenarios for chemicals across life-cycle stages, it is important also to consider the differences in the physiologic and pharmacokinetic factors for effected individuals at various life-stages. PBPK models have the capability to incorporate these physiological (e.g., body weight, fat percentage) and pharmacokinetic (e.g., metabolism rate, enzyme levels) variations in a study population. We plan to link probabilistic models of inter-individual variation in exposure and dosimetry using a modular exposure-to-dose approach to investigate the internal doses throughout the life-cycle. At this time it remains unknown whether this can be accomplished through a simple adaptation of an existing algorithm or will require development of a de novo approach. For modeling these linkages and doses, initially we will consider selecting chemicals such as flame retardants or other SVOCs in building materials in a relevant PBPK model for the human exposure modeling system. In particular, we may utilize the GastroPlus software tool and other PBPK related information from internal and external EPA collaborators during the development of the task-specific PBPK models. The goal of the PBPK modeling is to provide more rapid dose estimates across wider ranges of chemical space using widely available chemical and physiological parameters for relevant populations, life cycle stages, and time frames.

An overall goal of the research supported in part by this work assignment is an initial user interface to allow beta testing of a full modeling framework by the potential stakeholders. The model sensitivities and uncertainties will be assessed for each integrated modeling framework. Finally, several forms of model evaluation activities will be performed to ascertain the confidence in the model predictions. Individual modules of the modeling system can be evaluated independently (e.g., scenario definitions, emissions, concentrations, exposures), and overall model performance of the system can be evaluated methodically using biomonitoring data that is currently available (e.g., NHANES) or yet to be collected (e.g., by NIEHS/EPA Sister's Study Pilot project, Duke University's anticipated NIEHS-sponsored SVOC exposure and obesogens project). The biomarker data from such sources will be analyzed either directly or interpreted via reverse toxicokinetics (RTK) semi-empirical modeling methods.

This research project integrates emerging scientific information and tools from the LCA and chemical exposure and dose modeling areas. In particular, the integrated LCA/Exposure Modeling framework will provide the capability to rapidly assess environmental and human exposures to many chemicals and products over the life cycle of chemicals, to support the sustainability goals of CSS and other ORD integrated trans-disciplinary research areas. After environmental and human exposure assessments, the user will be able to identify the main life cycle stages that are influencing the evaluation results. The exposure and dose modeling tools will allow more rapid, flexible and reliable prediction of human exposures and doses for chemicals of interest to CSS within an enhanced LCA framework. The LCA exposure tool will be modular, which will facilitate further integration with ecological and hazard databases by separating inputs, model algorithms, and outputs of variability, sensitivity and uncertainty associated with the predictions.

### **III. STATEMENT OF WORK**

#### **Task 1: Human Behavior Components of Human Exposure Model (HEM)**

Recent research efforts at the EPA have focused on the modeling of human activity and behavior patterns, specifically with respect to behaviors which dictate the use of consumer products, using agent based modeling (ABM) methods. Under the direction of the WA-COR, the Contractor will take existing Python code which shows proof of concept of this method, and develop working R code which implements the method (i.e., the use of ABM to model human behaviors), and creates the independent module to be used in the HEM software to model human behavior.

**Deliverable:** ABM/Human behavior working module (i.e., R code), and appropriate documentation.



## **Task 2: Creation of Longitudinal Exposure Algorithms for HEM**

The HEM must have the capability to model longitudinal exposures via different pathway and routes. To this end, the contractor will develop and implement a longitudinal exposure module. This module will use as its basis the exposure scenario algorithm functions in SHEDS-HT, and take as inputs longitudinal patterns of consumer product use for individuals. The Contractor will develop a proposed approach after receiving initial technical guidance from the WA-COR. The proposed approach will include methods for addressing design issues identified by the WA-COR, including but not limited to implementing the SHEDS-HT fugacity model in a longitudinal manner, storing of longitudinal media concentrations, handling of carry-over exposures, handling of dermal removal process, and tracking of dermal loadings and pathway-specific exposures. The WA-COR will approve the proposed approach, upon which the Contractor will implement the method in R Code and complete a final memo describing the approach and code.

**Deliverable:** Memo describing proposed approach, resulting model code, and report of the results of model performance evaluation.

## **Task 3: Support for HEM**

Throughout development of the HEM model, various support will be needed in the development of individual modules. Support can be defined as (but not limited to): acquisition of additional data to be input into the CPDat database, refinements of the CPDat R package, assistance with IT issues related to making modules available as web-based tools, and writing code to create the control file/management module which will allow for interaction of all modules with each other.

**Deliverable 1:** Memo conveying the refinements and applications of CPDat R package, including the use of the composition tool database developed during Option 2. The report will also document how well the modules will have been integrated and any problems encountered during the integration.

**Deliverable 2:** Report describing proposed approach and resulting model code, and reporting the results of CPDat R package data and model quality evaluations.

## **Task 4: Additional Modules**

The HEM model is being created for application in a life cycle inventory and assessment framework. As such, the model will incorporate modules related to a variety of potential exposure pathways, including occupational exposures, end-of-life exposures, recycling exposures, and far-field exposures. Under the direction of the WA-COR, the Contractor will develop modules to support these additional exposure pathways.

In addition, the contractor will assist in writing programming code and support QA/QC of the SAS code for SHEDS-Multimedia (SHEDS-MM) as revised and updated to support the Office of Water's revision of the Lead and Copper Rule. This includes:

- 1) SHEDS-MM modification and programming and QA/QC-related activities;
- 2) Conduct QA/QC on input data, SAS codes and outputs;
- 3) SAS programing support for exposure modeling and data analyses

The SHEDS-MM work should be limited to:

- 1) 1) 4 meeting totaling 5 hours
- 2) 2) Modifying longitudinal assembling macro in SHEDS-MM

- 3) 3) Help with SAS code with length about 500 lines
- 4) 4) Checking 5-10 key SAS programs with total length of about 10000 lines (QA/QC).

**Deliverable:** Memo describing proposed approach and resulting model code, and reporting the results of model performance evaluation.

2-3-page report on the SHEDS-MM QA/QC.

#### **IV. ANTICIPATED DELIVERABLES**

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (likely to be Word, R, and Excel).

#### **V. DELIVERABLES AND SCHEDULE**

<b>Task 1.</b> Working model, code and documentation:	March 30, 2017
EPA Comments	21 work days after receipt of model.
Completed task	14 work days after receiving EPA comments.
<b>Task 2.</b> Memo conveying proposed approach:	February 28, 2017
EPA Response and recommendations memo	21 work days after receipt of memo
Completed task	21 work days after receiving EPA comments
<b>Task 3.</b> Memo conveying CPDat R package	July 31, 2017
EPA Comments	14 work days after receipt of memo.
Completed task	14 work days after receiving EPA comments
CPDat R report	September 10, 2017
EPA Comments	7 work days after receipt of ....
Completed task	5 work days after receiving EPA comments
<b>Task 4.</b>	
Memo describing proposed approach	21 work days after receipt of initial technical direction from WA-COR
Draft Model Code for generating longitudinal exposures	2 months after acceptance of proposed approach by WA-COR
Final Model code and documentation, including results of code testing	1 month after acceptance of draft model code
2-3 page report on the SHEDS-MM QA/QC.	2 months after acceptance of incremental work plan.

#### **VI. MANAGEMENT CONTROLS**

1. All deliverables shall be reviewed for conformance to the requirements of this WA before being approved as final.
2. The Contractor shall comply with other applicable requirements for final WA reports stipulated in contract.

## **VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The Contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the Contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or WA, the Contractor shall immediately contact the Work Assignment Contracting Officer Representative (COR), Project Officer (PO), or Contracting Officer (CO).

## **VIII. SPECIAL CONDITIONS AND ASSUMPTIONS**

The Contractor shall hold a conference call with the EPA COR at the initiation of the work assignment, and shall provide a bi-weekly update to the COR by telephone for the duration of the WA, in addition to the standard reporting requirements of the contract.

## **IX. EPA CONTACT INFORMATION**

Contracting Officer Representative: Daniel A. Vallero, PhD, NERL/HEASD, [vallero.daniel@epa.gov](mailto:vallero.daniel@epa.gov), 919-541-3306

Alternate COR: Peter P. Egeghy, PhD, NERL/HEASD, [egeghy.peter@epa.gov](mailto:egeghy.peter@epa.gov), 919-541-4103

## Appendix A

### Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

**FOCUS:** the work not only addresses the area of inquiry under consideration but also contributes to its understanding;

**VERIFY:** the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;

**INTEGRITY:** Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?

**RIGOR:** the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;

**UTILITY:** the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.

**CLARITY:** Is it written clearly and appropriately for the nature of the study?

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 4-75				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000003				
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 04/30/2019			Title of Work Assignment/SF Site Name				
			Base                      Option Period Number                      4			Human Exposure Models				
Contractor ICF Incorporated, L.L.C.					Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval					Period of Performance  From 11/01/2017 To 04/30/2019					
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> (Max 2)                      Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE:				
11/01/2013 To 04/30/2019										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:					Cost/Fee			LOE:		
Cumulative Approved:					Cost/Fee			LOE:		
Work Assignment Manager Name Daniel Vallero							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 919-541-3306			
							FAX Number:			
Project Officer Name Melissa Revely-Wilson							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 919-541-0207			
							FAX Number:			
Other Agency Official Name							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number:			
							FAX Number:			
Contracting Official Name William Yates							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 513-487-2055			
							FAX Number:			



**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA – 4-75 - Extension**

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**NOTE: This work assignment is a follow-on to work performed in the Year 4 Option Period under Work Assignment # 4-75. The work continues and provides additional product work performance and deliverables under Task 3 and Task 4 during the extension to Year 4 Option Period under Work Assignment 4-75.**

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**TITLE: Identification and adaptation of human exposure models to improve exposure factors in life cycle analysis applied to products and articles**

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**PERIOD OF PERFORMANCE:** 9/1/2018– 4/31/2019

**Specify Section & Paragraph SOW: (select all that apply)**

A. Assessment Issues and Documents

5. Integrated Science Assessments

B. Risk Assessment Methods Research and Development

F. Information Management

G. Literature Search

H. Physiologically-Based Pharmacokinetic (PBPK) Model Technical Support

**I. PURPOSE**

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) Human Exposure and Atmospheric Sciences Division of the National Exposure Research Laboratory, Office of Research and Development (ORD).

**II. BACKGROUND**

The EPA's Chemical Safety for Sustainability research program has been developing new ways to prioritize the chemicals that are ingredients of products and articles. This prioritization has addressed both the toxicity potential (i.e. ToxCast) and exposure potential (i.e. ExpoCast). Together, these will be the basis for improved methods and approaches for risk prioritization of chemicals as early as possible, with the objective of identifying chemicals before they reach the marketplace or before they are ingredients in products wherein the use would lead to unacceptable exposures. Within modern society, exposure to a wide range of chemicals through our daily habits and routines is ubiquitous and largely unavoidable. The initial focus to estimate exposure to chemicals in products used in microenvironments ( $\mu$ E) necessitates a "systems" model to delineate data needs arising from numerous knowledge bases to integrate product formulations, purchasing and use activities, and human activities.

Evaluating chemical safety and sustainability over the life cycle of chemicals requires drawing upon the various data streams and impact assessment tools from the life cycle assessment (LCA) field, along with improved exposure models that rapidly and reliably characterize exposures and human health impacts of chemicals from direct and indirect exposure pathways, which vary across their full life cycle. LCA has proven to be a valuable tool for systematically comparing processes and products; however, exposure assessment has almost exclusively been devoted to far-field scenarios. Integration of human exposure modeling of near-field scenarios into LCA will require bridging the scientific and technical gaps that currently prevent the harmonious use of the best available methods and tools from both fields. A critical linkage is the development of a modeling system



that makes use of existing stochastic and mechanistic human exposure models and will readily link to inputs and tools from the front-end life cycle inventory (LCI) and LCA modules; especially by enhancing the exposure factor in the calculation of the human health characterization factor.

The human exposure modeling elements of the overall research project will include the evaluation of existing model systems and appropriate adaptation of models to life cycle stages. The following life cycle stages are of particular interest in this effort, in order of priority:

- Residential/general population product use (near field exposure pathways)
- Occupational (professional) product use (near-field exposure pathways)
- Product end-of-life (recycling, reuse, disposal for near- and far-field exposure pathways)
- Product manufacturing (far-field and near-field exposure pathways)
- Chemical manufacturing (far-field and near-field exposure pathways)

Initial research efforts will focus on adapting and integrating near-field residential and general population exposure models into the life cycle framework, and extension of the models to near-field occupational (professional) product use. Evaluation, selection, and adaptation of end-of-life and occupational manufacturing models and modeling approaches is envisioned as a longer-term goal of this effort. Potential collaborations with NIOSH or other relevant organizations for occupational manufacturing exposure modeling will be explored.

The key expectation of this research is more reliable and better human health characterization factors (CFs) through enhancement of exposure metrics within the CF calculation. For residential (and professional) product use, the research builds directly upon recent advances in exposure-based chemical prioritization, ExpoCast, and SHEDS-HT (Stochastic Human Exposure and Dose Simulation, High-Throughput model), and will complement the CSS Rapid Exposure & Dosimetry Project. In particular, the research will leverage the knowledge gained through application of SHEDS-HT to provide higher-throughput estimates of exposure to chemicals in consumer products and articles, based on product chemical function and composition databases (e.g., CPcat and CPCPdb, respectively). The LCI and LCA approaches will benefit from evaluation tools for sustainable manufacturing of chemicals (e.g., GREENSCOPE) for providing specific information at a sub-process level for LCI generation.

Over the FY15-16 time period, SHEDS-HT will be adapted for application in a life cycle inventory and assessment framework. This includes improved time-location-activity diary and dietary algorithms and modification of SHEDS-HT modules to support additional pertinent near- and far-field exposure scenarios. In the longer time frame, near-field model results will be combined with information from other models for chemical/product manufacturing, use and disposal and fate and transport. Moreover, the human exposure modeling system will be developed to be flexible enough to accommodate the LCI and other LCA inputs, scenarios or processes. The project will also include various means of incorporating exposure information into characterization factors, e.g. adaptation of intake fractions, especially the product intake fraction (PiF), which can be combined with toxicity factors, e.g. ToxCast activity concentrations.

Scenario development is an important part of this effort and will be used to define and guide human exposure modeling system development. The system will represent far-field and near-field exposure scenarios. Existing models, especially USEtox, show promise in informing far-field aspects of each life cycle, including the end-of-life outputs. Likewise, SHEDS-HT may be a starting point for near-field models, beginning with residential product and article use and possible adaptation to professional product use. However, other models may be considered and adapted as appropriate. As such, literature reviews will be conducted to determine the relevance and quality of models and databases available, especially for the non-residential scenarios and for end-of-life aspects of these and other LCA stages.

In addition, to simulate different exposure and dose scenarios for chemicals across life-cycle stages, it is important also to consider the differences in the physiologic and pharmacokinetic factors for effected individuals at various life-stages. PBPK models have the capability to incorporate these physiological (e.g., body weight, fat percentage) and pharmacokinetic (e.g., metabolism rate, enzyme levels) variations in a study population. We plan to link probabilistic models of inter-individual variation in exposure and dosimetry using a modular exposure-to-dose approach to investigate the internal doses throughout the life-cycle. At this time it remains unknown whether this can be accomplished through a simple adaptation of an existing algorithm or will require development of a de novo approach. For modeling these linkages and doses, initially we will consider selecting chemicals such as flame retardants or other SVOCs in building materials in a relevant PBPK model for the human exposure modeling system. In particular, we may utilize the GastroPlus software tool and other PBPK related information from internal and external EPA collaborators during the development of the task-specific PBPK models. The goal of the PBPK modeling is to provide more rapid dose estimates across wider ranges of chemical space using widely available chemical and physiological parameters for relevant populations, life cycle stages, and time frames.

An overall goal of the research supported in part by this work assignment is an initial user interface to allow beta testing of a full modeling framework by the potential stakeholders. The model sensitivities and uncertainties will be assessed for each integrated modeling framework. Finally, several forms of model evaluation activities will be performed to ascertain the confidence in the model predictions. Individual modules of the modeling system can be evaluated independently (e.g., scenario definitions, emissions, concentrations, exposures), and overall model performance of the system can be evaluated methodically using biomonitoring data that is currently available (e.g., NHANES) or yet to be collected (e.g., by NIEHS/EPA Sister's Study Pilot project, Duke University's anticipated NIEHS-sponsored SVOC exposure and obesogens project). The biomarker data from such sources will be analyzed either directly or interpreted via reverse toxicokinetics (RTK) semi-empirical modeling methods.

This research project integrates emerging scientific information and tools from the LCA and chemical exposure and dose modeling areas. In particular, the integrated LCA/Exposure Modeling framework will provide the capability to rapidly assess environmental and human exposures to many chemicals and products over the life cycle of chemicals, to support the sustainability goals of CSS and other ORD integrated trans-disciplinary research areas. After environmental and human exposure assessments, the user will be able to identify the main life cycle stages that are influencing the evaluation results. The exposure and dose modeling tools will allow more rapid, flexible and reliable prediction of human exposures and doses for chemicals of interest to CSS within an enhanced LCA framework. The LCA exposure tool will be modular, which will facilitate further integration with ecological and hazard databases by separating inputs, model algorithms, and outputs of variability, sensitivity and uncertainty associated with the predictions.

### **III. STATEMENT OF WORK**

#### **Task 1: Human Behavior Components of Human Exposure Model (HEM)**

Recent research efforts at the EPA have focused on the modeling of human activity and behavior patterns, specifically with respect to behaviors which dictate the use of consumer products, using agent based modeling (ABM) methods. Under the direction of the WA-COR, the Contractor will take existing Python code which shows proof of concept of this method, and develop working R code which implements the method (i.e., the use of ABM to model human behaviors), and creates the independent module to be used in the HEM software to model human behavior.

**Deliverable:** ABM/Human behavior working module (i.e., R code), and appropriate documentation. **(COMPLETED)**

## **Task 2: Creation of Longitudinal Exposure Algorithms for HEM**

The HEM must have the capability to model longitudinal exposures via different pathway and routes. To this end, the contractor will develop and implement a longitudinal exposure module. This module will use as its basis the exposure scenario algorithm functions in SHEDS-HT, and take as inputs longitudinal patterns of consumer product use for individuals. The Contractor will develop a proposed approach after receiving initial technical guidance from the WA-COR. The proposed approach will include methods for addressing design issues identified by the WA-COR, including but not limited to implementing the SHEDS-HT fugacity model in a longitudinal manner, storing of longitudinal media concentrations, handling of carry-over exposures, handling of dermal removal process, and tracking of dermal loadings and pathway-specific exposures. The WA-COR will approve the proposed approach, upon which the Contractor will implement the method in R Code and complete a final memo describing the approach and code.

**Deliverable:** Memo describing proposed approach, resulting model code, and report of the results of model performance evaluation. **(COMPLETED)**

## **Task 3: Support for HEM**

Throughout development of the HEM model, various support will be needed in the development of individual modules. Support can be defined as (but not limited to): acquisition of additional data to be input into the CPDat database, refinements of the CPDat R package, assistance with IT issues related to making modules available as web-based tools, and writing code to create the control file/management module which will allow for interaction of all modules with each other.

**Deliverable 1:** Memo conveying the refinements and applications of CPDat R package, including the use of the composition tool database developed during Option 2. The report will also document how well the modules will have been integrated and any problems encountered during the integration. **(COMPLETED)**

**Deliverable 2:** Report describing proposed approach and resulting model code, and reporting the results of CPDat R package data and model quality evaluations. **(COMPLETED)**

**Deliverable 3:** Revised version of model code, including appropriate edits to model documentation, addressing key issues raised by reviewers during external letter review process.

**Deliverable 4:** Memo describing analysis implemented (under technical direction of EPA) and resulting model code, for analyzing, summarizing, and plotting HEM model results for case studies.

## **Task 4: Additional Modules**

The HEM model is being created for application in a life cycle inventory and assessment framework. As such, the model will incorporate modules related to a variety of potential exposure pathways, including occupational exposures, end-of-life exposures, recycling exposures, and far-field exposures. Under the direction of the WA-COR, the Contractor will develop modules to support these additional exposure pathways.

Specifically, in support of the expansion of HEM's multimedia capabilities the contractors shall (following technical direction and consultation) add the following new exposure algorithms, modules, or pathways to the existing code:



1. Implement the dietary exposure pathway in HEM. This may require:
  - Addition of required consumption and food residue input files (including development of appropriate daily consumption diaries from the NHANES-What We Eat in America Study)
  - Addition of food ingestion exposure function/module and addition of food exposures to current aggregate ingestion variables
  - Addition of a food ingestion variable in relevant output files
2. Implement the article emission pathway in HEM Source to Dose module. This may require:
  - Addition of emission methods analogous to those implemented in SHEDS-HT to the indirect pathway of HEM S-to-D module (e.g., emission based on the steady-state gas phase concentration  $y_0$ , with partitioning to air/dust/surfaces via the fugacity model, and subsequent exposure via surface contact (dermal/hand-to-mouth) and inhalation)
  - Adaptation/change of fugacity model or the S-to-D indirect pathway (if needed) to implement these methods
  - Addition of article contribution to indirect exposure to output file (if possible, based on algorithm implementation)
3. Implement ambient pathway in HEM Source-to-Dose module. This may require:
  - Addition of an outdoor/ambient concentration component to the indirect pathway of the HEM S-to-D module, i.e. a non-zero outdoor compartment that results in a steady-state input source to the residential air compartment of the fugacity model

The contractor shall also update the existing HEM documentation for the above code changes.

**Deliverable 1:** Memo describing proposed approach and resulting model code, and reporting the results of model performance evaluation (**COMPLETED**)

**Deliverable 2:** Updated HEM code and documentation incorporating the above algorithms.

#### **IV. ANTICIPATED DELIVERABLES**

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (likely to be Word, R, and Excel).

#### **V. DELIVERABLES AND SCHEDULE**

<b>Task 1.</b> Working model, code and documentation:	March 30, 2017 - Completed
EPA Comments	21 work days after receipt of model.
Completed task	14 work days after receiving EPA comments.
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Completed task	21 work days after receiving EPA comments
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EPA Comments	7 work days after receipt of ....
Completed task	5 work days after receiving EPA comments
<b>Task 4.</b>	
Memo describing proposed approach	21 work days after receipt of initial technical direction from WA-COR
Draft Model Code for generating longitudinal exposures	2 months after acceptance of proposed approach by WA-COR
Final Model code and documentation, including results of code testing	1 month after acceptance of draft model code
Schedule meeting with EPA to discuss implementation and receive technical direction	Upon approval of Work Plan
Draft model code for implementing ambient air pathway	2 weeks after receiving technical direction
Draft model code for implementing article pathways	6 weeks after receiving technical direction
Draft model code for implementing dietary pathways	12 weeks after receiving technical direction
Final model code and documentation, including results of code testing	1 month after acceptance of final iteration of draft model code

## **VI. MANAGEMENT CONTROLS**

1. All deliverables shall be reviewed for conformance to the requirements of this WA before being approved as final.
2. The Contractor shall comply with other applicable requirements for final WA reports stipulated in contract.

## **VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The Contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the Contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or WA, the Contractor shall immediately contact the Work Assignment Contracting Officer Representative (COR), Project Officer (PO), or Contracting Officer (CO).

## **VIII. SPECIAL CONDITIONS AND ASSUMPTIONS**

The Contractor shall hold a conference call with the EPA COR at the initiation of the work assignment, and shall provide a bi-weekly update to the COR by telephone for the duration of the WA, in addition to the standard reporting requirements of the contract.

#### **IX. EPA CONTACT INFORMATION**

Contracting Officer Representative: Daniel A. Vallero, PhD, NERL/HEASD, [vallero.daniel@epa.gov](mailto:vallero.daniel@epa.gov), 919-541-3306

Alternate COR: Peter P. Egeghy, PhD, NERL/HEASD, [egeghy.peter@epa.gov](mailto:egeghy.peter@epa.gov), 919-541-4103



## Appendix A

### Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

**FOCUS:** the work not only addresses the area of inquiry under consideration but also contributes to its understanding;

**VERIFY:** the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;

**INTEGRITY:** Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?

**RIGOR:** the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;

**UTILITY:** the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.

**CLARITY:** Is it written clearly and appropriately for the nature of the study?

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 4-77								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001								
Contract Number EP-C-14-001	Contract Period   11/01/2013   To   04/30/2019 Base                      Option Period Number      4	Title of Work Assignment/SF Site Name Standards for Pathogens								
Contractor ICF Incorporated, L.L.C.		Specify Section and paragraph of Contract SOW								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From   11/29/2017   To   04/30/2019								
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
11/01/2013   To   04/30/2019										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee				LOE:		
Cumulative Approved:				Cost/Fee				LOE:		
Work Assignment Manager Name   Gary Russo  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number: 202-566-1335			
							FAX Number:			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number: 919-541-0207			
							FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number:			
							FAX Number:			
Contracting Official Name   William M. Yates  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number: 513-487-2055			
							FAX Number:			

**PERFORMANCE WORK STATEMENT  
ICF CONTRACT EP-C-14-001  
WORK ASSIGNMENT 4-77**

**Title:** Secondary Contact Water Quality Standards for Pathogens

**Work Assignment Manager (WAM):** Gary Russo (Mail Code 4305T)  
Standards and Health Protection Division  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460  
Phone (202) 566-1335  
E-mail: [russo.gary@epa.gov](mailto:russo.gary@epa.gov)

**Alternate WAM:** Shari Barash (Mail Code 4305T)  
Standards and Health Protection Division  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460  
Phone (202) 566-0996  
E-mail: [barash.shari@epa.gov](mailto:barash.shari@epa.gov)

**Period of Performance:** January 1, 2018 through October 31, 2018

**Contractor SOW:** III.D, III.E.1, III.G

**CBI:** No confidential business information will be needed for this work assignment.

**Background:**

EPA's bacteriological water quality criteria under section 304(a) of the Clean Water Act (CWA) address water quality standards for "primary contact" recreational uses and do not significantly address "secondary contact" recreational uses. Primary contact recreation is typically defined as water-based recreational activities that could be expected to result in the ingestion of or immersion in water such as swimming, water skiing, or surfing. Secondary contact recreation is typically defined as water-based recreational activities where contact with the water is either incidental or accidental, and the probability of ingesting appreciable quantities of water is minimal.

Current EPA policy allows States, tribes and territories to adopt bacteriological criteria for secondary contact uses that are less stringent than criteria for primary contact uses. The

justification for less stringent secondary contact criteria is based on the assumption that secondary contact activities are associated with exposure to fewer pathogenic organisms. It is believed that a higher concentration of pathogens in water is counterbalanced by a lower potential exposure to those pathogens, resulting in the same risk of illness in secondary recreational activities as risks associated with primary recreational activities. However, the potential for pathogen exposure during different recreational activities is not well characterized, and there is currently no scientific consensus on whether or not they are in fact associated with different risks of illness (differential risk).

Although there is a body of scientific literature addressing the risk of illness associated with various water-based recreational activities, the relationships between different activities, water quality, and health risks are not well understood. The wide ranges of existing studies often have ambiguous results or support conflicting conclusions. Such ambiguity and/or disagreement may be due to a variety of reasons, including differences in the questions being addressed, differences, biases and/or flaws in the way the studies were designed or conducted, differences in interpretation of the study results, or simply due to chance.

The purpose of this project is to examine the evidence for or against differential risk by conducting a systematic review. A systematic review is a specific type of literature review that focuses on a specific research question and tries to identify, appraise, select and synthesize all high quality research and evidence relevant to that question. The overall goal of a systematic review is to provide an objective and transparent synthesis of research results that minimizes bias. The systematic review will provide an up-to-date, state-of-the-art evaluation of the current scientific knowledge of the health risks associated with different water-based recreational activities in water contaminated by fecal material. The results and conclusions of the systematic review will be used to inform EPA policies and decisions associated with recreational water quality standards for the protection of public health.

This work assignment is a follow-on to work performed in the Year 3 Option Period under Work Assignment # 3-77. The work continues from Task 2 and 3 during this Year 4 Option Period under Work Assignment 4-77.

### **Performance Work Statement (PWS):**

The scope of work in this PWS will fall under the following tasks:

#### **Task 1 – Work plan, quality assurance, and monthly progress reports**

##### **Task Area 1.1 - Work plan**

The contractor shall develop a work plan to address all tasks in the PWS. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the

contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If one or more subcontractor(s) are proposed and they are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. The number and professional level of hours charged and total dollars for each task will be provided. Other costs greater than \$100.00 shall be itemized.

- Deliverable – Work plan.
- Deadline – Fifteen (15) calendar days after receipt of work assignment

#### Task Area 1.2 - Quality assurance

Work assignments 1-10, 2-10, 3-10, and 4-10 under contract EP-C-11-005, and work assignment 2-77 and 3-77 under contract EP-C-14-001 required the use of existing data. Consistent with the Agency's quality assurance (QA) requirements, the contractor developed a contract-level quality assurance project plan (QAPP) and project-level QAPP to assure the quality of the existing data or any other types of data used in these work assignments. The contractor addressed the project-specific QA requirements in the previous work plans and monthly progress reports following Attachment 1 entitled: "QAPP requirements for projects using existing data." The QAPPs were approved by the EPA before activities using existing data began. In addition to the project-specific QAPP, the contractor developed a systematic review protocol that contained QA and quality control (QC) procedures for implementing the systematic review. **The contractor shall continue to implement all QA and QC procedures specified in the contract-level QAPP, project-level QAPP, and systematic review protocol for all work performed under this PWS.**

Upon completion of the systematic review, the contractor shall complete the EPA Office of Water Information Quality Guidelines checklist and supporting narrative (see Attachment 2).

- Deliverable – Completed Information Quality Guidelines checklist
- Deadline – Seven (7) calendar days following technical direction from EPA WAM.

#### Task Area 1.3 - Monthly Progress Reports

The contractor shall provide progress and financial reports to the EPA WAM each month. The contractor shall also provide any information related to the execution of this PWS whenever requested by the EPA WAM. The progress report shall indicate, in a separate QA/QC section, whether QA/QC issues have been identified and how they will be resolved. If significant QA/QC issues are encountered, the contractor shall contact the EPA WAM immediately to discuss the issue. If work ceases because of QA/QC issues, the contractor shall not resume work until receiving written approval from the EPA WAM. Monthly financial reports shall at



minimum include a table with the invoice LOE and costs for each task and task area in this PWS.

## **Task 2 – Finalize and publish systematic review**

### Task Area 2.1 - Finalize draft manuscript

The contractor shall finalize the draft manuscript developed during the previous work assignment for submission to a scientific journal. The manuscript shall be organized thoughtfully, written concisely, grammatically correct, academically rigorous, contain high quality tables and figures when appropriate, and formatted for the journal being targeted. The contractor shall develop the manuscript in a way that provides for efficient reformatting for submission to other scientific journals if needed. The contractor shall work closely with the EPA WAM and discuss all significant decisions and options while developing the manuscript.

- Deliverable – Final manuscript.
- Deadline – Thirty (30) days after receiving direction from the EPA WAM to begin finalizing the draft manuscript.

### Task Area 2.2 - Response to reviewer comments

After EPA submits the manuscript to the publisher of the scientific journal, the publisher may request revisions to the manuscript in response to reviewer comments. If the publisher requests revisions to the manuscript in response to reviewer comments, the contractor shall work closely with the EPA WAM to develop point-by-point written responses to the reviewer comments for submission to the journal editor. The contractor shall also prepare the Information Quality Guidelines Checklist necessary for products that EPA disseminates to the public under EPA's Information Quality Guidelines. The contractor shall work closely with the EPA WAM and discuss all significant decisions and options while developing the response to reviewer comments.

- Deliverable – Response to comments document and Information Quality Guidelines Checklist.
- Deadline – Fifteen (15) days after manuscript revisions are completed and the contractor receives written instruction from the EPA WAM to begin development of response to comments.

### Task Area 2.3 – Manuscript revisions in response to peer-review

After developing responses to reviewer comments, the contractor shall work closely with the EPA WAM to determine the appropriate manuscript revisions. After the EPA WAM determines the appropriate manuscript revisions, the contractor shall revise the manuscript in response to the



reviewer comments as instructed by the EPA WAM. The contractor shall only make those revisions directed by the EPA WAM. The contractor shall conform to the same standards of quality when revising the manuscript as specified above for finalizing the manuscript. The manuscript shall be organized thoughtfully, written concisely, grammatically correct, academically rigorous, contain high quality tables and figures when appropriate, and formatted for the journal being targeted. The contractor shall develop the manuscript in a way that provides for efficient reformatting for submission to other scientific journals if needed. The contractor shall work closely with the EPA WAM and discuss all significant decisions and options while finalizing the manuscript.

- Deliverable – Final manuscript.
- Deadline – Thirty (30) days after contractor completes responses to reviewer comments and receives instructions from EPA WAM to begin manuscript revisions.

### **Task Area 3 - General Project Support**

Task Area 3.1 - Prepare briefing materials and other supporting documents pertaining to the systematic review

Briefing materials and other supporting documents will be needed during the systematic review development process and after the review is published. The contractor shall aid in the development of any materials or presentations for these purposes. This may include but is not limited to preparing interim project updates and other materials for internal and external audiences as requested by the EPA WAM, briefing documents, PowerPoint presentations, and other supporting documents as needed. The contractor may be requested by the EPA WAM to participate in and/or conduct briefings or participate in seminars or talks related to the systematic review.

- Deliverable – Requested materials and supporting documents.
- Deadline – As mutually agreed upon by the EPA WAM and contractor

Task Area 3.2 - Support options development and analyses for potential changes to EPA policies related to bacteriological water quality standards.

As the results and conclusions of the systematic review become clear, the EPA may want to consider alternative policies related to bacteriological water quality standards. The contractor shall aid in the development of potential alternative policy options. These activities may include, but are not limited to, performing additional research and analysis of existing scientific data and information, analysis of the potential public health outcomes resulting from policy modifications,

and the analysis of water quality standard implementation implications associated with the adoption of alternative bacteriological water quality standards. The contractor may be requested to participate in and/or conduct briefings or other presentations related to this work.

- Deliverable – Requested materials.
- Deadline – As mutually agreed upon by the EPA WAM and contractor

### **Travel:**

Travel may be needed as deemed necessary by the EPA WAM. No contractor travel outside of the Washington, D.C. metro area is required.

### **Knowledge and Skills Required:**

The contractor shall have the necessary scientific knowledge and expertise to develop the aforementioned materials in this PWS that are high quality and use state-of-the-art methods. Specifically, the contractor shall have experience designing, performing, and publishing primary scientific research evaluating the health effects of environmental pollution, as well as experience designing, performing, and publishing systematic- and meta-analyses of such studies. The contractor shall have expertise in epidemiological studies that evaluate microbiological water pollution using fecal indicator organisms. The contractor shall be proficient in advanced state-of-the-art statistical methods typically used to analyze epidemiological studies and perform meta-analyses. The contractor should also be competent in analytical methods used to monitor microbial water pollution (including molecular techniques), the determination of human exposure to environmental contaminant sources, and disease endpoints related to microbial exposure through contact with water.

### **General Requirements of the Work Assignment and Schedule:**

#### Due Dates

The contractor shall mutually acceptable due dates with EPA WAM. The contractor shall notify the EPA WAM in advance, if a due date will not be met and negotiate a mutually acceptable revised due date.

#### Delays

The contractor shall provide sufficient qualified man-power to ensure there are no avoidable delays. If a delay outside the control of the contractor is unavoidable, the contractor shall immediately notify the EPA WAM and negotiate a mutually acceptable revised schedule.

### Draft Documents

The contractor shall submit draft or interim work products requested by the EPA WAM. Draft or interim work products shall be prepared in an electronic format compatible with Microsoft Office 2013 and Endnote X. The EPA WAM will provide the contractor with comments on draft work products in electronic format. Work products shall be deemed draft until designated as final by the EPA WAM.

### Final Documents

The contractor shall submit final documents electronically to the EPA WAM.

### **Meetings, Conferences, Training Events, Award Ceremonies and Receptions:**

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA WAM as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA WAM.

## **ATTACHMENT 1**

### **QAPP Requirement for Projects Using Existing Data**

A project involving existing data gathers and uses existing data for purposes other than those for which they may have been originally collected. These existing data may be obtained from many sources including literature, industry, computerized databases and information systems, and computerized or mathematical models of environmental processes. For projects that use existing data, a QAPP shall be prepared that includes the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the existing data. The following requirements should be addressed as applicable.

#### **Section 1. Project Objectives, Organization, and Responsibilities**

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The existing data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical or other types of data analysis. Assumptions and or recommendations based on the data analysis shall also be included if applicable.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

#### **Section 2. Sources of Existing Data**

- 2.1 The source(s) of the existing data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the existing data will be identified in any project deliverable.

#### **Section 3. Quality of Existing Data**

- 3.1 Quality requirements of the existing data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

- 3.2 The procedures for determining the quality of the existing data shall be described.
- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the existing data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the existing data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

#### **Section 4. Data Reporting, Data Reduction, and Data Validation**

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (e.g., journal article, final report, etc.).



## **ATTACHMENT 2**

### **Office of Water**

#### **Information Quality Guidelines:**

#### **Pre-Dissemination Review Guidance and Checklists**

version 2.2 (January 10, 2003)

### **BACKGROUND**

In order to comply with Section 515 of the Treasury and General Government Appropriations Act for FY 2002 (Public Law 106-554), the Office of Management and Budget developed guidelines that “provide policy and procedural guidance for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies.”

In response to OMB’s guidelines (FRL-7157-8, March 2002), EPA developed the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (The Guidelines), which contains EPA’s policy and procedural guidance for ensuring and maximizing the quality of the information we disseminate. “Quality” refers to objectivity, integrity, and utility.

The Guidelines also:

- Outline administrative mechanisms for EPA pre-dissemination review of information products.
- Enable affected persons to file complaints regarding disseminated information that they believe to be noncompliant with EPA’s Guidelines.

Implementation began **October 1, 2002**.

For more information, visit <http://www.epa.gov/oei/qualityguidelines/>

In order to ensure that information meets The Guidelines, the following guidance and checklists should be used prior to dissemination.

### **OVERVIEW**

- What information is covered under The Guidelines?

version 2.2 (January 10, 2003)

- Is your organization in compliance with EPA's existing Quality System and Office of Water's Quality Management Plan?
- What type of information do I have?
- Do additional guidelines apply for externally gathered data?
- Checklists for Pre-Dissemination Review
- What are Requests for Correction and Requests for Reconsideration, and how does OW respond to them?

## **WHAT INFORMATION IS COVERED UNDER THE GUIDELINES?**

These guidelines apply only to information EPA disseminates to the public.

### What DO The Guidelines cover?

- EPA prepares the information and distributes it to support or represent EPA's viewpoint, or to formulate or support a regulation, guidance, or other Agency decision or position.
- EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it.
- EPA reviews and comments on information distributed by an outside party in a manner that indicates EPA is endorsing it, directs the outside party to disseminate it on EPA's behalf, or otherwise adopts or endorses it.

### What DON'T The Guidelines cover?

- Distribution of information for government employees
- EPA response to FOIA, FACA, or similar legislation
- Correspondence directed to individuals or persons
- Information presented solely to Congress
- Ephemeral information (press releases, fact sheets, press conferences)
- Background information (published articles distributed by libraries, or other non-EPA endorsed distributions)
- Information distributed by recipients of EPA grants, contracts, or cooperative agreements unless EPA adopts or endorses the information
- Information in public filings, including information submitted to EPA, either voluntarily or under mandates/requirements
- Distribution of information in judicial cases or administrative adjudication

## **IS YOUR ORGANIZATION IN COMPLIANCE WITH EPA'S EXISTING QUALITY SYSTEM AND OFFICE OF WATER'S QUALITY MANAGEMENT PLAN?**

Many of EPA's current quality assurance practices fulfill much of EPA's Information Quality Guidelines. Examples of these policies are: Quality System, Peer Review, Action Development Process, Integrated Error Correction Process, Information Resources Management Manual, Risk Characterization Policy and Handbook, Program-Specific Policies, and EPA's Commitment to Continuous Improvement. EPA information disseminated to the public must meet EPA's already existing Quality System and other related policies. The Quality System utilizes a graded approach to establish quality criteria that are appropriate for the intended use of the information and the resources available. (The Quality System can be found in EPA Order 5360.1 A2, "Policy and Program Requirements for the Mandatory Agency-wide Quality System" and in the "EPA Quality Manual".)

The Quality System requires Agency organizations to:

- Assign a quality assurance manager
- Develop a Quality Management Plan
- Conduct an annual assessment of the organization's quality system
- Use a systematic planning process to develop acceptance or performance criteria prior to the initiation of all projects that involve environmental information collection and/or use
- Develop Quality Assurance Project Plans for all applicable projects and tasks involving environmental data
- Conduct an assessment of existing data, when used to support Agency decisions or other secondary purposes, to verify accuracy
- Implement all Agency-wide Quality System components in all applicable EPA-funded extramural agreements
- Provide appropriate training for all levels of management and staff

The Office of Water implements EPA's Quality System through its Quality Management Plan, approved by OEI in September 2001. Please refer to this document to ensure that the information you are disseminating complies with Office of Water quality assurance policies.

## **WHAT TYPE OF INFORMATION DO I HAVE?**

Different quality standards apply to influential information, influential scientific risk assessment information, and non-influential information. The definitions of these three types of information are:

Influential: when the Agency can reasonably determine that dissemination of the information will have a clear and substantial impact on important public policies or private sector decisions. These include OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis. Influential information must meet a higher standard of quality: “reproducibility”.

Reproducibility: providing enough information to allow the public to reproduce our analyses

Influential Scientific Risk Assessment: applies to all dissemination of information regarding human health, environmental, or safety risk assessments, except those conducted under the Safe Drinking Water Act, which will adhere to SDWA principles. Information is required to be accurate, reliable, and unbiased; it should also be comprehensive, informative, and understandable. The quality standard is “objectivity,” and uses the following principles:

- Information is accurate, reliable, and unbiased. This involves:
  - Best available science, which utilizes sound and objective scientific practices, and peer review when available
  - Data collection by accepted methods
- Presentation of information is consistent with the purpose of the information, is comprehensive, informative, and understandable. This means specifying:
  - each population addressed by the risk
  - expected risk or central estimate
  - upper-bound and lower-bound estimate of risk
  - significant uncertainties identified
  - peer reviewed studies known to the Administrator

Non-Influential: standard of quality is “transparency.”

Transparency: the public can understand how conclusions were obtained on the information

## **DO ADDITIONAL GUIDELINES APPLY FOR EXTERNALLY GATHERED DATA?**

Most external environmental data is within the scope of the Quality System. This includes literature, industry surveys, compilations from computerized databases and information systems, and results from computerized or mathematical models of environmental processes and conditions.

Regarding voluntarily submitted information, EPA will continue to work with States and other governments, the scientific and technical community, and other interested information providers to develop and publish criteria the EPA would use to assess this type of information.

**Depending on your information, you need only fill out ONE of the following three checklists. Please forward the checklists to OW's Information Quality Guidelines Officer (currently Leo Gueriguian, 564-0388) for approval and signature. The checklist must then be signed by your Division Director, and a copy sent to your Quality Assurance Officer. Please also note that outside entities may file Requests for Correction (i.e. complaints) to EPA, citing non-compliance with EPA's Information Quality Guidelines.**

**\*\*Note: OGWDW staff should send their completed checklists directly to their Division Directors. They should work with the OW IQ Guidelines Officer, as their projects and checklists are being developed.**



## Office of Water

### Information Quality Guidelines Checklist for

#### Influential Information

Influential Information has or will have a clear and substantial impact on important public policies or private sector decisions. (Includes OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis.)

- ☐ The information to be disseminated is covered under The Guidelines.
- ☐ The information is in compliance with EPA's Quality System and other related policies.
- ☐ The information is in compliance with Office of Water's Quality Management Plan.
- ☐ The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
  - ☐ Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
  - ☐ Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
  - ☐ Utility: the information is useful to the intended users.
- ☐ The information meets "reproducibility" standard.

The information and its accompanying documentation has a higher degree of transparency regarding the following:

  - ☐ The source of the data used
  - ☐ The various assumptions employed
  - ☐ The analytic methods applied
  - ☐ The statistical procedures employed

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Division Director's Signature & Date

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IQG Officer for OW Signature & Date

(Officer signature Not needed for OGWDW staff)

\*\*If your information does not comply with any of these items, please attach brief explanation of any omissions. Please forward a copy of this document to your office's Quality Assurance Officer.

## Office of Water

### Information Quality Guidelines Checklist for

#### Influential Risk Assessment Information

Influential Scientific Risk Assessment Information has or will have a clear and substantial impact on important public policies or private sector decisions. (Includes OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis.)

- ☐ The information to be disseminated is covered under The Guidelines.
- ☐ The information is in compliance with EPA's Quality System and other related policies.
- ☐ The information is in compliance with Office of Water's Quality Management Plan.
- ☐ The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
  - ☐ Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
  - ☐ Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
  - ☐ Utility: the information is useful to the intended users.
- ☐ The information meets "objectivity" standard.
  - ☐ The information is accurate, reliable, and unbiased:
    - best available science and supporting studies conducted using sound and objective scientific practices, including peer reviewed studies
    - data were collected by accepted methods or best available methods (if the method's reliability nature of the decision justifies the use of the data)
  - ☐ Presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable. Each of the following must be specified:
    - each population addressed by the risk or each risk assessment endpoint addressed by any estimate of applicable ecological risk
    - expected risk or central estimate for the specific populations affected or the ecological assessment endpoints
    - upper-bound and lower-bound estimate of risk
    - significant uncertainties identified, and studies that would assist in resolving uncertainties

-peer reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to reconcile inconsistencies in the scientific data

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Division Director's Signature & Date

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IQG Officer for OW Signature & Date

(Officer signature Not needed for OGWDW staff)

\*\*If your information does not comply with any of these items, please attach brief explanation of any omissions.  
Please forward a copy of this document to your office's Quality Assurance Officer.

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 4-77								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001								
Contract Number EP-C-14-001	Contract Period   11/01/2013   To   04/30/2019 Base                      Option Period Number      4	Title of Work Assignment/SF Site Name Standards for Pathogens								
Contractor ICF Incorporated, L.L.C.		Specify Section and paragraph of Contract SOW								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From   11/29/2017   To   04/30/2019								
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: 11/01/2013   To   04/30/2019		Cost/Fee:				LOE:				
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee				LOE:				
Cumulative Approved:		Cost/Fee				LOE:				
Work Assignment Manager Name   Gary Russo  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 202-566-1335 FAX Number:			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name   William M. Yates  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:			

**PERFORMANCE WORK STATEMENT AMENDMENT  
ICF CONTRACT EP-C-14-001  
WORK ASSIGNMENT 4-77**

**Title:** Secondary Contact Water Quality Standards for Pathogens

**Work Assignment Manager (WAM):** Gary Russo (Mail Code 4305T)  
Standards and Health Protection Division  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460  
Phone (202) 566-1335  
E-mail: [russo.gary@epa.gov](mailto:russo.gary@epa.gov)

**Alternate WAM:** Shari Barash (Mail Code 4305T)  
Standards and Health Protection Division  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460  
Phone (202) 566-0996  
E-mail: [barash.shari@epa.gov](mailto:barash.shari@epa.gov)

**Period of Performance:** November 1, 2018 through April 30, 2019

**Contractor SOW:** III.D, III.E.1, III.G

**CBI:** No confidential business information will be needed for this work assignment.

**Background:**

EPA's bacteriological water quality criteria under section 304(a) of the Clean Water Act (CWA) address water quality standards for "primary contact" recreational uses and do not significantly address "secondary contact" recreational uses. Primary contact recreation is typically defined as water-based recreational activities that could be expected to result in the ingestion of or immersion in water such as swimming, water skiing, or surfing. Secondary contact recreation is typically defined as water-based recreational activities where contact with the water is either incidental or accidental, and the probability of ingesting appreciable quantities of water is minimal.

Current EPA policy allows States, tribes and territories to adopt bacteriological criteria for secondary contact uses that are less stringent than criteria for primary contact uses. The

justification for less stringent secondary contact criteria is based on the assumption that secondary contact activities are associated with exposure to fewer pathogenic organisms. It is believed that a higher concentration of pathogens in water is counterbalanced by a lower potential exposure to those pathogens, resulting in the same risk of illness in secondary recreational activities as risks associated with primary recreational activities. However, the potential for pathogen exposure during different recreational activities is not well characterized, and there is currently no scientific consensus on whether or not they are in fact associated with different risks of illness (differential risk).

Although there is a body of scientific literature addressing the risk of illness associated with various water-based recreational activities, the relationships between different activities, water quality, and health risks are not well understood. The wide ranges of existing studies often have ambiguous results or support conflicting conclusions. Such ambiguity and/or disagreement may be due to a variety of reasons, including differences in the questions being addressed, differences, biases and/or flaws in the way the studies were designed or conducted, differences in interpretation of the study results, or simply due to chance.

The purpose of this project is to examine the evidence for or against differential risk by conducting a systematic review. A systematic review is a specific type of literature review that focuses on a specific research question and tries to identify, appraise, select and synthesize all high quality research and evidence relevant to that question. The overall goal of a systematic review is to provide an objective and transparent synthesis of research results that minimizes bias. The systematic review will provide an up-to-date, state-of-the-art evaluation of the current scientific knowledge of the health risks associated with different water-based recreational activities in water contaminated by fecal material. The results and conclusions of the systematic review will be used to inform EPA policies and decisions associated with recreational water quality standards for the protection of public health.

This work assignment amendment specifies additional work (task 4) that builds on the work performed under tasks 1 – 3 of the original work assignment.

#### **Performance Work Statement (PWS) Amendment:**

The following additional task shall constitute the scope of work for this PWS amendment:



**Task Area 4 – Develop A Scientifically Defensible Method To Derive And/Or Evaluate Alternative Water Quality Criteria On The Basis Of Differences In Illness Risk Associated With Different Recreational Activities**

Task Area 4.1 – Develop the scientifically defensible method.

Some states and tribes adopt water quality criteria for certain recreational activities commonly referred to as “secondary contact” that are less stringent than EPA’s 304(a) recommendation for “primary contact” on the basis of the assumption that a lower probability of exposure compensates for a higher pathogen concentration resulting in the same risk of illness. However, there is no scientific evidence supporting this assumption, and thus no scientific basis for EPA to review and act on state submissions of “secondary contact” criteria.

The systematic review and meta-analysis resulting from the work in Tasks 1 – 3 evaluate the current scientific evidence for differences in risk of illness associated with different types of recreational activities. One result of this evaluation will be numerical estimates of illness risk associated with different types of recreational activities. The contractor shall develop a scientifically defensible method that allows the use of illness risk estimates from the systematic review and EPA’s 2012 Recreational Water Quality Criteria for primary contact recreation to develop and/or evaluate water quality criteria for non-primary contact activities. The contractor shall provide a written document describing the method, its appropriate application, and limitations. The document shall provide sufficient detail to allow internal EPA and external peer review. The EPA WAM may request the contractor participate in and/or conduct briefings or other presentations related to this work.

- Deliverable – Draft document describing the method, how it was derived, appropriate application, and limitations.
- Deadline – No later than February 1, 2019.
- Deliverable – Draft document describing the method, how it was derived, appropriate application, and limitations.
- Deadline – No later than April 1, 2019.

Task Area 4.2 – Ancillary support.

Additional ancillary support related to the deliverables in this expanded WA may also be needed. The contractor shall aid in the development of such materials as determined by the EPA WAM. This may include but is not limited to responding to comments and questions on draft materials, further research and development, additional unanticipated work necessary to publish the manuscript developed under Task 2, preparing interim project updates, preparing other materials for internal and external audiences as requested by the EPA WAM, briefing documents, PowerPoint presentations, and other supporting documents as needed. The contractor may be

requested by the EPA WAM to participate in and/or conduct briefings or participate in seminars or talks related to the systematic review.

- Deliverable – Requested materials and supporting documents.
- Deadline – As mutually agreed upon by the EPA WAM and contractor.

#### **Travel:**

Travel may be needed as deemed necessary by the EPA WAM. No contractor travel outside of the Washington, D.C. metro area is required.

#### **Knowledge and Skills Required:**

The contractor shall have the necessary scientific knowledge and expertise to develop the aforementioned materials in this PWS that are high quality and use state-of-the-art methods. Specifically, the contractor shall have experience designing, performing, and publishing primary scientific research evaluating the health effects of environmental pollution, as well as experience designing, performing, and publishing systematic- and meta-analyses of such studies. The contractor shall have expertise in epidemiological studies that evaluate microbiological water pollution using fecal indicator organisms. The contractor shall be proficient in advanced state-of-the-art statistical methods typically used to analyze epidemiological studies and perform meta-analyses. The contractor should also be competent in analytical methods used to monitor microbial water pollution (including molecular techniques), the determination of human exposure to environmental contaminant sources, and disease endpoints related to microbial exposure through contact with water.

#### **General Requirements of the Work Assignment and Schedule:**

##### Due Dates

The contractor shall mutually acceptable due dates with EPA WAM. The contractor shall notify the EPA WAM in advance, if a due date will not be met and negotiate a mutually acceptable revised due date.

##### Delays

The contractor shall provide sufficient qualified man-power to ensure there are no avoidable delays. If a delay outside the control of the contractor is unavoidable, the contractor shall immediately notify the EPA WAM and negotiate a mutually acceptable revised schedule.

##### Draft Documents

The contractor shall submit draft or interim work products requested by the EPA WAM. Draft or interim work products shall be prepared in an electronic format compatible with Microsoft Office 365 and Endnote X. The EPA WAM will provide the contractor with comments on draft

work products in electronic format. Work products shall be deemed draft until designated as final by the EPA WAM.

#### Final Documents

The contractor shall submit final documents electronically to the EPA WAM.

#### **Meetings, Conferences, Training Events, Award Ceremonies and Receptions:**

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA WAM as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA WAM.

## **ATTACHMENT 1**

### **QAPP Requirement for Projects Using Existing Data**

A project involving existing data gathers and uses existing data for purposes other than those for which they may have been originally collected. These existing data may be obtained from many sources including literature, industry, computerized databases and information systems, and computerized or mathematical models of environmental processes. For projects that use existing data, a QAPP shall be prepared that includes the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the existing data. The following requirements should be addressed as applicable.

#### **Section 1. Project Objectives, Organization, and Responsibilities**

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The existing data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical or other types of data analysis. Assumptions and or recommendations based on the data analysis shall also be included if applicable.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

#### **Section 2. Sources of Existing Data**

- 2.1 The source(s) of the existing data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the existing data will be identified in any project deliverable.

#### **Section 3. Quality of Existing Data**

- 3.1 Quality requirements of the existing data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

- 3.2 The procedures for determining the quality of the existing data shall be described.
- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the existing data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the existing data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

#### **Section 4. Data Reporting, Data Reduction, and Data Validation**

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (e.g., journal article, final report, etc.).

## **ATTACHMENT 2**

### **Office of Water**

#### **Information Quality Guidelines:**

#### **Pre-Dissemination Review Guidance and Checklists**

version 2.2 (January 10, 2003)

### **BACKGROUND**

In order to comply with Section 515 of the Treasury and General Government Appropriations Act for FY 2002 (Public Law 106-554), the Office of Management and Budget developed guidelines that “provide policy and procedural guidance for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies.”

In response to OMB’s guidelines (FRL-7157-8, March 2002), EPA developed the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (The Guidelines), which contains EPA’s policy and procedural guidance for ensuring and maximizing the quality of the information we disseminate. “Quality” refers to objectivity, integrity, and utility.

The Guidelines also:

- Outline administrative mechanisms for EPA pre-dissemination review of information products.
- Enable affected persons to file complaints regarding disseminated information that they believe to be noncompliant with EPA’s Guidelines.

Implementation began **October 1, 2002**.

For more information, visit <http://www.epa.gov/oei/qualityguidelines/>

In order to ensure that information meets The Guidelines, the following guidance and checklists should be used prior to dissemination.

### **OVERVIEW**

- What information is covered under The Guidelines?

version 2.2 (January 10, 2003)



- Is your organization in compliance with EPA's existing Quality System and Office of Water's Quality Management Plan?
- What type of information do I have?
- Do additional guidelines apply for externally gathered data?
- Checklists for Pre-Dissemination Review
- What are Requests for Correction and Requests for Reconsideration, and how does OW respond to them?

## **WHAT INFORMATION IS COVERED UNDER THE GUIDELINES?**

These guidelines apply only to information EPA disseminates to the public.

### What DO The Guidelines cover?

- EPA prepares the information and distributes it to support or represent EPA's viewpoint, or to formulate or support a regulation, guidance, or other Agency decision or position.
- EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it.
- EPA reviews and comments on information distributed by an outside party in a manner that indicates EPA is endorsing it, directs the outside party to disseminate it on EPA's behalf, or otherwise adopts or endorses it.

### What DON'T The Guidelines cover?

- Distribution of information for government employees
- EPA response to FOIA, FACA, or similar legislation
- Correspondence directed to individuals or persons
- Information presented solely to Congress
- Ephemeral information (press releases, fact sheets, press conferences)
- Background information (published articles distributed by libraries, or other non-EPA endorsed distributions)
- Information distributed by recipients of EPA grants, contracts, or cooperative agreements unless EPA adopts or endorses the information
- Information in public filings, including information submitted to EPA, either voluntarily or under mandates/requirements
- Distribution of information in judicial cases or administrative adjudication

## **IS YOUR ORGANIZATION IN COMPLIANCE WITH EPA'S EXISTING QUALITY SYSTEM AND OFFICE OF WATER'S QUALITY MANAGEMENT PLAN?**

Many of EPA's current quality assurance practices fulfill much of EPA's Information Quality Guidelines. Examples of these policies are: Quality System, Peer Review, Action Development Process, Integrated Error Correction Process, Information Resources Management Manual, Risk Characterization Policy and Handbook, Program-Specific Policies, and EPA's Commitment to Continuous Improvement. EPA information disseminated to the public must meet EPA's already existing Quality System and other related policies. The Quality System utilizes a graded approach to establish quality criteria that are appropriate for the intended use of the information and the resources available. (The Quality System can be found in EPA Order 5360.1 A2, "Policy and Program Requirements for the Mandatory Agency-wide Quality System" and in the "EPA Quality Manual".)

The Quality System requires Agency organizations to:

- Assign a quality assurance manager
- Develop a Quality Management Plan
- Conduct an annual assessment of the organization's quality system
- Use a systematic planning process to develop acceptance or performance criteria prior to the initiation of all projects that involve environmental information collection and/or use
- Develop Quality Assurance Project Plans for all applicable projects and tasks involving environmental data
- Conduct an assessment of existing data, when used to support Agency decisions or other secondary purposes, to verify accuracy
- Implement all Agency-wide Quality System components in all applicable EPA-funded extramural agreements
- Provide appropriate training for all levels of management and staff

The Office of Water implements EPA's Quality System through its Quality Management Plan, approved by OEI in September 2001. Please refer to this document to ensure that the information you are disseminating complies with Office of Water quality assurance policies.

## **WHAT TYPE OF INFORMATION DO I HAVE?**

Different quality standards apply to influential information, influential scientific risk assessment information, and non-influential information. The definitions of these three types of information are:

Influential: when the Agency can reasonably determine that dissemination of the information will have a clear and substantial impact on important public policies or private sector decisions. These include OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis. Influential information must meet a higher standard of quality: “reproducibility”.

Reproducibility: providing enough information to allow the public to reproduce our analyses

Influential Scientific Risk Assessment: applies to all dissemination of information regarding human health, environmental, or safety risk assessments, except those conducted under the Safe Drinking Water Act, which will adhere to SDWA principles. Information is required to be accurate, reliable, and unbiased; it should also be comprehensive, informative, and understandable. The quality standard is “objectivity,” and uses the following principles:

- Information is accurate, reliable, and unbiased. This involves:
  - Best available science, which utilizes sound and objective scientific practices, and peer review when available
  - Data collection by accepted methods
- Presentation of information is consistent with the purpose of the information, is comprehensive, informative, and understandable. This means specifying:
  - each population addressed by the risk
  - expected risk or central estimate
  - upper-bound and lower-bound estimate of risk
  - significant uncertainties identified
  - peer reviewed studies known to the Administrator

Non-Influential: standard of quality is “transparency.”

Transparency: the public can understand how conclusions were obtained on the information

## **DO ADDITIONAL GUIDELINES APPLY FOR EXTERNALLY GATHERED DATA?**

Most external environmental data is within the scope of the Quality System. This includes literature, industry surveys, compilations from computerized databases and information systems, and results from computerized or mathematical models of environmental processes and conditions.

Regarding voluntarily submitted information, EPA will continue to work with States and other governments, the scientific and technical community, and other interested information providers to develop and publish criteria the EPA would use to assess this type of information.

**Depending on your information, you need only fill out ONE of the following three checklists. Please forward the checklists to OW's Information Quality Guidelines Officer (currently Leo Gueriguian, 564-0388) for approval and signature. The checklist must then be signed by your Division Director, and a copy sent to your Quality Assurance Officer. Please also note that outside entities may file Requests for Correction (i.e. complaints) to EPA, citing non-compliance with EPA's Information Quality Guidelines.**

**\*\*Note: OGWDW staff should send their completed checklists directly to their Division Directors. They should work with the OW IQ Guidelines Officer, as their projects and checklists are being developed.**

## Office of Water

### Information Quality Guidelines Checklist for

#### Influential Information

Influential Information has or will have a clear and substantial impact on important public policies or private sector decisions. (Includes OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis.)

- ☐ The information to be disseminated is covered under The Guidelines.
- ☐ The information is in compliance with EPA's Quality System and other related policies.
- ☐ The information is in compliance with Office of Water's Quality Management Plan.
- ☐ The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
  - ☐ Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
  - ☐ Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
  - ☐ Utility: the information is useful to the intended users.
- ☐ The information meets "reproducibility" standard.

The information and its accompanying documentation has a higher degree of transparency regarding the following:

  - ☐ The source of the data used
  - ☐ The various assumptions employed
  - ☐ The analytic methods applied
  - ☐ The statistical procedures employed

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Division Director's Signature & Date

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IQG Officer for OW Signature & Date

(Officer signature Not needed for OGWDW staff)

\*\*If your information does not comply with any of these items, please attach brief explanation of any omissions. Please forward a copy of this document to your office's Quality Assurance Officer.

## Office of Water

### Information Quality Guidelines Checklist for

#### Influential Risk Assessment Information

Influential Scientific Risk Assessment Information has or will have a clear and substantial impact on important public policies or private sector decisions. (Includes OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis.)

- ☐ The information to be disseminated is covered under The Guidelines.
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- ☐ The information is in compliance with Office of Water's Quality Management Plan.
- ☐ The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
  - ☐ Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
  - ☐ Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
  - ☐ Utility: the information is useful to the intended users.
- ☐ The information meets "objectivity" standard.
  - ☐ The information is accurate, reliable, and unbiased:
    - best available science and supporting studies conducted using sound and objective scientific practices, including peer reviewed studies
    - data were collected by accepted methods or best available methods (if the method's reliability nature of the decision justifies the use of the data)
  - ☐ Presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable. Each of the following must be specified:
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    - expected risk or central estimate for the specific populations affected or the ecological assessment endpoints
    - upper-bound and lower-bound estimate of risk
    - significant uncertainties identified, and studies that would assist in resolving uncertainties



-peer reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to reconcile inconsistencies in the scientific data

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Division Director's Signature & Date

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IQG Officer for OW Signature & Date

(Officer signature Not needed for OGWDW staff)

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<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 4-81				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   10/31/2018 Base                      Option Period Number       4			Title of Work Assignment/SF Site Name Vulnerability of Human Health				
Contractor ICF Incorporated, L.L.C.					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/01/2017   To   10/31/2018				
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE:				
11/01/2013   To   10/31/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:					Cost/Fee		LOE:			
Cumulative Approved:					Cost/Fee		LOE:			
Work Assignment Manager Name   Janet Gamble  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:				
						Phone Number: 703-347-8617				
						FAX Number:				
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:				
						Phone Number: 919-541-0207				
						FAX Number:				
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:				
						Phone Number:				
						FAX Number:				
Contracting Official Name   William Yates  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:				
						Phone Number: 513-487-2055				
						FAX Number:				

# PERFORMANCE WORK STATEMENT

Contract # EP-C-14-001

WA Option # 4-81

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**Title:** Mapping the Vulnerability of Human Health to Climate Change in the United States

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**PERIOD of PERFORMANCE:** 11/01/2017 – 10/31/2018

**Specify Section & Paragraph SOW:** A., A.2.d., A.3., B. B.1.g., C.1., C.4., D., E & F

**NOTE:** This work assignment is a follow-on to work performed in the Year 3 Option Period under Work Assignment # 3-81. The work continues for Task 6 during this Year 4 Option Period under Work Assignment # 4-81. This PWS outlines the Task 6 Deliverable. Tasks 1-4 and part of Task 5 have been completed. No new funds are included in this WA # 4-81, rather, those funds remaining from Option Year 3 are to be rolled forward.

## I. PURPOSE

The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's National Center for Environmental Assessment (NCEA), Global Change Research Program (GCRP) for developing methodologies for mapping the impacts of climate change on the vulnerability of human health and well-being in the U.S. and considering the adaptation strategies that may be supported by vulnerability maps.

## II. OBJECTIVES

This project addresses a seemingly modest but complex question: "How straightforward is it to map the vulnerability of human health, across a number of factors or dimensions, for the entire United States in a meaningful and self-consistent way (see U.S. EPA, 2011)?"

The overarching objective for this project is to provide public health, public safety, urban planning, emergency response officials and other stakeholders with geospatial methods and maps for identifying and understanding key vulnerabilities, communicating risks to vulnerable populations, and planning and prioritizing location-specific adaptation responses. Other objectives include:

- Identifying and summarizing an array of indicators that may be used to derive vulnerability maps;
- Engaging subject matter experts (SMEs) to identify approaches currently used to assess vulnerability, map health impacts, and prepare location-specific adaptation strategies.

Mapping vulnerability is conceptually and technically demanding. We are exploring key challenges associated with vulnerability mapping, especially the lack of consensus regarding mapping methods and the result that some analytic approaches have, at times, been based on convenience or familiarity as opposed to efficacy, generalizability, and comparability. This project will compile guidance for vulnerability mapping, including:

- Research to identify and evaluate mapping methodologies for understanding vulnerabilities (including, local, regional, and national map overlays) to climate-related stressors and to the interaction with other demographic, socioeconomic and environmental stressors.
- A survey of applications that support information integration for standardizing and mapping spatial data drawn from large health, demographic, land use / land cover, climate data sets, and other important data sources.

- Making the connection between vulnerability mapping and approaches for adaptation, especially addressing opportunities for improved risk communication and targeted emergency response and,
- Determining how uncertainty, model complexity, generalizability, and comparability can be addressed across a range of mapping methodologies.

This project focuses on a “hands on” approach. The intended audience for the vulnerability maps is expected to include professionals engaged in community-based research and adaptation planning, community and urban planners and geographers; land use and transportation planners; public health and safety officials; emergency preparedness and response professionals; environmental health scientists; community organizers; and, other stakeholders, both in and out of government and academia and other non-governmental organizations (NGOs) across national, regional, state and local scales.

### **III. BACKGROUND**

The National Center for Environmental Assessment (NCEA) in the Office of Research and Development (ORD) at the U.S. Environmental Protection Agency (EPA) focuses on the impacts of weather extremes on human health, air quality, water quality, and aquatic ecosystems. Impacts include, but are not limited to, increases in warmer and more frequent hot days and nights; increases in excess heat events; increases in heavy precipitation and flooding; increases in areas affected by drought and wildfires; increases in the intensity of tropical storms and storm surge; and sea level rise (Melillo 2014). In addition to weather-related factors contributing to health outcomes, human health is influenced by non-weather factors, such as economic status, the adoption of new technologies, the condition of the built environment and infrastructure, available human and social capital, political and social institutions, land-use / land-cover changes, demographic trends, accessibility and affordability of health care, and specific health impacts.

Within the United States, weather extremes are expected to contribute to a range of health impacts for vulnerable populations. The extent and nature of those impacts on human health vary by location, by the relative vulnerability of specific population groups, by the extent and duration of exposure to extreme weather events, and by society’s ability to adapt to or cope with weather extremes.

We propose to identify and define methodologies for developing maps and mapping tools that allow for an assessment of the health impacts of weather extremes on vulnerable populations. Using GIS tools, analysts can develop maps that demonstrate the impacts of extreme weather events, tropical storms, river and coastal flooding, droughts and wildfires, extreme heat, and sea level rise. An index of adaptive capacity (which is a function of factors such as income, life expectancy, educational attainment, literacy, adoption of new technologies, and condition of existing infrastructure) can also be mapped.

Some satellite remote-sensing instruments now have a degree of spatial resolution that allows for finer-scale analyses. High-resolution remote sensing technologies enable the mapping of land cover and land use, and thermal profiles and can be integrated, through the use of Geographic Information Systems (GIS), with indicators of social vulnerability such as demographic trends, income, measures of economic productivity, condition of housing stocks, extent of air-conditioning usage, access to and the condition of transportation infrastructure, and accessible and affordable health care services. The refinement of mapping techniques may mean that emergency personnel will improve their response to extreme events and allow better resource allocation and tailoring of communications and adaptation strategies for vulnerable populations in at-risk locations.

Prior to the initiation of this WA, EPA staff will review the draft findings from a literature review conducted as part of the US Global Change Research Program’s Climate Health Assessment to identify projects, reports, or indicators, focused on mapping vulnerability of human health to climate change. EPA staff is developing a survey of vulnerability mapping projects that introduces a conceptual framework that defines vulnerability

mapping and highlights mapping studies for which data sources may be available. Existing or planned projects that employ mapping methodologies will incorporate a variety of materials, including: peer reviewed journals, grey literature, conference proceedings and reports, NGO and Government reports, and information describing existing vulnerability mapping projects, and health indicators.

The USGCRP Climate Health Assessment includes a chapter on Populations of Concern (Chapter 9) that addresses health impacts and vulnerability mapping across population groups. In addition, the EPA Staff has begun to identify and classify vulnerability mapping projects with information that includes: investigator contact information; location and scale of project; vulnerability indicators used; data sources and their availability, utility and reliability; methodologies used for developing map overlays; types of spatial-analytic techniques employed; approaches for disseminating maps and creating visualization of risks; and, lessons learned from each mapping project.

#### **IV. INTENDED AUDIENCE and UTILIZATION of PROJECT PRODUCTS.**

The intended audience/user for this project's outputs is the Office of Air and Radiation (OAR) Climate Change Division (CCD) and partners from the Sustainable and Healthy Communities (SHC) National Program at EPA/ORD and outside public health researchers, practitioners, and policy planners. Representatives from these audiences may be invited to participate in the one-on-one interviews and the experts' technical working group meeting. Other EPA Program and Regional Offices are expected to utilize the report and its mapping methodologies and analyses to understand the vulnerability of populations to the health impacts associated with weather extremes based on geographic location. We will seek input from federal agencies represented in the membership of the USGCRP's Climate Change and Human Health Working Group (CCHHG). We anticipate opportunities to present this project to and seek engagement from federal partners in the CCHHG. Subject matter experts will be identified by federal, state, and local mapping experts from within and outside of government. The non-governmental experts are limited to nine or fewer. The total of federal, academic and NGO SMEs is eleven.

#### **V. REQUIRED CONTRACTOR QUALIFICATIONS.**

The Contractor shall provide multidisciplinary professional expertise in assessing the impacts of weather extremes on human health and human well-being, especially related to developing best practices for applying geo-spatial mapping techniques to assess the vulnerability of specific locations/populations to the human health impacts of weather extremes. Expertise related to vulnerability mapping and public health adaptation strategies that address weather-related impacts is required. In addition, experience is required in preparing technical reports consistent with the standards of the peer-reviewed literature. The proposed scientific and technical authors shall be recognized in their fields, and they shall have the general knowledge, as well as the specific knowledge, expertise, or experience, specified in the work assignment. The selected authors must have experience that includes authoring journal articles or other technical documents that specifically relate to this topic.

#### **VI. BACKGROUND related to Option Years 2 and 3 on WA # 2-81 and WA # 3-81, Tasks 1-5**

**NOTE:** Tasks 1-5 from Option Years 2 and 3 are complete. This work assignment # 4-81 is a follow-on to work performed in the Year 2 and Year 3 Option Periods under Work Assignments # 2-81 and # 3-81. The work continues for Task 6 during this Year 4 Option Period under Work Assignment # 4-81.

**Summary of completed Tasks 1-5:** An initial Synthesis Report entitled "Mapping the Vulnerability of Human Health to Climate Change in the United States" was prepared by the Contractor using the transcripts from the one-on-one interviews with the eleven Subject Matter Experts (SMEs) conducted in April, 2016. The WAM



reviewed and edited this initial report and forwarded it to the SMEs for their review prior to the August 12, 2016 SME workshop in Washington, DC. At the workshop and following, additional input was received from the SMEs and transcripts of the workshop were prepared by the Contractor and provided to the WAM. Using the transcripts from the workshop, the WAM revised the Synthesis Report and prepared an Internal Review Draft (IRD) for review by 2 EPA scientists. The WAM prepared a response to the internal reviews and edited the report to address those comments. The WAM prepares the External Review Draft (ERD) based on responses to the IRD review process. The contractor provided some formatting assistance to prepare the document to go out for external review.

## **VII. UPDATED STATEMENT of WORK for Option Year 4, WA 4-81, Task 6**

### **Option Year 4, Task 6: Response to External Review**

**NOTE on Background:** Under a separate peer review contract, NCEA arranged for an external peer review by letter. The peer review contractor recruited 3 external reviewers and solicited their response to the External Review Draft. The peer review contractor compiles those comments. Once completed, the external peer review responses and the compiled comments will be handed off by the peer review contractor to the WAM for transmittal to ICF (the contractor for this work assignment EP-C-14-001).

**Deliverable 6.1:** Using the compiled external reviewer comments, the Contractor shall prepare a response to comments document and a Draft Final Report and provide both to the WAM for final review and editing.

## **VIII. DELIVERABLE TIMELINE for WA # 4-81, Task 6**

<b>Task</b>	<b>Description</b>	<b>Deliverable Timeline</b>
<b>TASK 6</b>	<b>A Final Report shall be prepared based on the external review comments</b>	
6.1	Using the compiled external reviewer comments, the Contractor shall prepare a response to comments document and complete an updated final draft. Both the response to comments and the updated draft will be provided to the WAM for final review and editing.	FY 2018 Q2



## **IX. MANAGEMENT CONTROLS**

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

## **X. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO.

## **XI. SPECIAL CONDITIONS AND ASSUMPTIONS**

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment and shall provide a monthly update to the WAM via the monthly invoice for the duration of the work assignment.

## **XII. EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the WAM.

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